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Part 1

HELPING OUR SENIOR POPULATION IN COMFORT ENVIRONMENTS ACT

DECEMBER 17, 2020.—Ordered to be printed

Mr. NEAL, from the Committee on Ways and Means, submitted the following

R E P O R T

[To accompany H.R. 5821]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 5821) to amend title XVIII of the Social Security Act to establish hospice program survey and enforcement procedures under the Medicare program, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Helping Our Senior Population in Comfort Environments Act" or the "HOSPICE Act".

SEC. 2. ESTABLISHING HOSPICE PROGRAM SURVEY AND ENFORCEMENT PROCEDURES UNDER THE MEDICARE PROGRAM.

(a) SURVEY AND ENFORCEMENT PROCEDURES.—

(1) IN GENERAL.—Part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) is amended by adding at the end the following new section:

"SEC. 1822. HOSPICE PROGRAM SURVEY AND ENFORCEMENT PROCEDURES.

"(a) SURVEYS.—

"(1) FREQUENCY.—Any entity that is certified as a hospice program shall be subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months (and not less frequently than once every 24 months beginning October 1, 2021).

"(2) PUBLIC TRANSPARENCY OF SURVEY AND CERTIFICATION INFORMATION.—

"(A) SUBMISSION OF INFORMATION TO THE SECRETARY.—

"(i) IN GENERAL.—Each State, and each national accreditation body with respect to which the Secretary has made a finding under section 1865(a) respecting the accreditation of a hospice program by such body, shall submit, in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph, information respecting any survey or certification made with respect to a hospice program by such State or body, as applicable. Such information shall include any inspection report made by such State or body with respect to such survey or certification, any enforcement actions taken as a result of such survey or certification, and any other information determined appropriate by the Secretary.

"(ii) REQUIRED INCLUSION OF SPECIFIED FORM.—With respect to a survey under this subsection carried out by a national accreditation body described in clause (i) on or after October 1, 2021, information described in such clause shall include Form 2567 (or a successor form), along with such additional information determined appropriate by such body.

"(B) PUBLIC DISCLOSURE OF INFORMATION.—Beginning not later than October 1, 2022, the Secretary shall publish the information submitted under subparagraph (A) on the public website of the Centers for Medicare & Medicaid Services in a manner that is prominent, easily accessible, readily understandable, and searchable. The Secretary shall provide for the timely update of such information so published.

"(3) CONSISTENCY OF SURVEYS.—Each State and the Secretary shall implement programs to measure and reduce inconsistency in the application of survey results among surveyors.

"(4) SURVEY TEAMS.—

"(A) IN GENERAL.—In the case of a survey conducted under this subsection on or after October 1, 2021, by more than 1 individual, such survey shall be conducted by a multidisciplinary team of professionals (including a registered professional nurse).

"(B) PROHIBITION OF CONFLICTS OF INTEREST.—Beginning October 1, 2021, a State may not use as a member of a survey team under this subsection an individual who is serving (or has served within the previous 2 years) as a member of the staff of, or as a consultant to, the program surveyed respecting compliance with the requirements of section 1861(dd) or who has a personal or familial financial interest in the program being surveyed.

"(C) TRAINING.—The Secretary shall provide, not later than October 1, 2021, for the comprehensive training of State and Federal surveyors, and any surveyor employed by a national accreditation body described in paragraph (2)(A)(i), in the conduct of surveys under this subsection, including training with respect to the review of written plans for providing hospice care (as described in section 1814(a)(7)(B)). No individual shall serve as a member of a survey team with respect to a survey conducted on or after such date unless the individual has successfully completed a training and

testing program in survey and certification techniques that has been approved by the Secretary.

"(5) FUNDING.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 to the Centers for Medicare & Medicaid Program Management Account, of $10,000,000 for each fiscal year (beginning with fiscal year 2022) for purposes of carrying out surveys under this subsection. Sums so transferred shall remain available until expended. Any transfer pursuant to this paragraph shall be in addition to any transfer pursuant to section 3(a)(2) of the Improving Medicare Post-Acute Care Transformation Act of 2014.

"(b) SPECIAL FOCUS PROGRAM.—

"(1) IN GENERAL.—The Secretary shall conduct a special focus program for enforcement of requirements for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements of this Act.

"(2) PERIODIC SURVEYS.—Under such special focus program, the Secretary shall conduct surveys of each hospice program in the special focus program not less than once every 6 months.

"(c) ENFORCEMENT.—

"(1) SITUATIONS INVOLVING IMMEDIATE JEOPARDY.—If the Secretary determines on the basis of a standard survey or otherwise that a hospice program that is certified for participation under this title is no longer in compliance with the requirements specified in section 1861(dd) and determines that the deficiencies involved immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy described in paragraph (5)(B)(iii) or terminate the certification of the program, and may provide, in addition, for 1 or more of the other remedies described in paragraph (5)(B).

"(2) SITUATIONS NOT INVOLVING IMMEDIATE JEOPARDY.—If the Secretary determines on the basis of a standard survey or otherwise that a hospice program that is certified for participation under this title is no longer in compliance with the requirements specified in section 1861(dd) and determines that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary may (for a period not to exceed 6 months) impose remedies developed pursuant to paragraph (5)(A), in lieu of terminating the certification of the program. If, after such a period of remedies, the program is still no longer in compliance with such requirements, the Secretary shall terminate the certification of the program.

"(3) PENALTY FOR PREVIOUS NONCOMPLIANCE.—If the Secretary determines that a hospice program that is certified for participation under this title is in compliance with the requirements specified in section 1861(dd) but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil monetary penalty under paragraph (5)(B)(i) for the days in which the Secretary finds that the program was not in compliance with such requirements.

"(4) OPTION TO CONTINUE PAYMENTS FOR NONCOMPLIANT HOSPICE PROGRAMS.—The Secretary may continue payments under this title with respect to a hospice program not in compliance with the requirements specified in section 1861(dd) over a period of not longer than 6 months, if—

"(A) the State or local survey agency finds that it is more appropriate to take alternative action to assure compliance of the program with such requirements than to terminate the certification of the program;

"(B) the program has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action; and

"(C) the program agrees to repay to the Federal Government payments received under this title during such period if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by hospice programs under this paragraph.

"(5) REMEDIES.—

"(A) DEVELOPMENT.—

"(i) IN GENERAL.—Not later than October 1, 2021, the Secretary shall develop and implement—

"(I) a range of remedies to apply to hospice programs under the conditions described in paragraphs (1) through (4); and

"(II) appropriate procedures for appealing determinations relating to the imposition of such remedies.

Remedies developed pursuant to the preceding sentence shall include the remedies specified in subparagraph (B).

"(ii) CONDITIONS OF IMPOSITION OF REMEDIES.—Not later than October 1, 2021, the Secretary shall develop and implement specific procedures with respect to the conditions under which each of the remedies developed under clause (i) is to be applied, including the amount of any fines and the severity of each of these remedies. Such procedures shall be designed so as to minimize the time between identification of deficiencies and imposition of these remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies.

"(B) SPECIFIED REMEDIES.—The remedies specified in this subparagraph are the following:

"(i) Civil monetary penalties in an amount not to exceed $10,000 for each day of noncompliance by a hospice program with the requirements specified in section 1861(dd).

"(ii) Suspension of all or part of the payments to which a hospice program would otherwise be entitled under this title with respect to items and services furnished by a hospice program on or after the date on which the Secretary determines that remedies should be imposed pursuant to paragraph (2).

"(iii) The appointment of temporary management to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made in order to bring the program into compliance with all such requirements.

"(C) PROCEDURES.—

"(i) CIVIL MONETARY PENALTIES.—

"(I) IN GENERAL.—Subject to subclause (II), the provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(II) RETENTION OF AMOUNTS FOR HOSPICE PROGRAM IMPROVEMENTS.—The Secretary may provide that any portion of civil monetary penalties collected under this subsection may be used to support activities that benefit individuals receiving hospice care, including education and training programs to ensure hospice program compliance with the requirements of section 1861(dd).

"(ii) SUSPENSION OF PAYMENT.—A finding to suspend payment under subparagraph (B)(ii) shall terminate when the Secretary finds that the program is in substantial compliance with all such requirements.

"(iii) TEMPORARY MANAGEMENT.—The temporary management under subparagraph (B)(iii) shall not be terminated until the Secretary has determined that the program has the management capability to ensure continued compliance with all the requirements referred to in such subparagraph.

"(D) RELATIONSHIP TO OTHER REMEDIES.—The remedies developed under subparagraph (A) are in addition to sanctions otherwise available under State or Federal law and shall not be construed as limiting other remedies, including any remedy available to an individual at common law.".

(2) AVAILABILITY OF HOSPICE ACCREDITATION SURVEYS.—Section 1865(b) of the Social Security Act (42 U.S.C. 1395bb(b)) is amended by inserting "or, beginning on the date of the enactment of the HOSPICE Act, a hospice program" after "home health agency".

(3) STATE PROVISION OF HOSPICE PROGRAM INFORMATION.—

(A) IN GENERAL.—Section 1864(a) of the Social Security Act (42 U.S.C. 1395aa(a)) is amended in the sixth sentence—

(i) by inserting "and hospice programs" after "information on home health agencies";

(ii) by inserting "or the hospice program" after "the home health agency";

(iii) by inserting "or the hospice program" after "with respect to the agency"; and

(iv) by inserting "and hospice programs" after "with respect to home health agencies".

(B) EFFECTIVE DATE.—The amendments made by subparagraph (A) shall apply with respect to agreements entered into on or after, or in effect as of, the date that is 1 year after the date of the enactment of this Act.

(4) CONFORMING AMENDMENTS.—

(A) DEFINITION OF A HOSPICE PROGRAM.—Section 1861(dd)(4) of the Social Security Act (42 U.S.C. 1395x(dd)(4)) is amended by striking subparagraph (C).

(B) CONTINUATION OF FUNDING.—Section 3(a)(2) of the Improving Medicare Post-Acute Care Transformation Act of 2014 is amended by inserting "and section 1822(a)(1) of such Act," after "as added by paragraph (1),".

(b) INCREASING PAYMENT REDUCTIONS FOR FAILURE TO MEET QUALITY DATA REPORTING REQUIREMENTS.—Section 1814(i)(5)(A)(i) of the Social Security Act (42 U.S.C. 1395f(i)(5)(A)(i)) is amended by inserting "(or, for fiscal year 2023 and each subsequent fiscal year, 4 percentage points)" before the period.

(c) REPORT.—Not later than 36 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report containing an analysis of the effects of the amendments made by subsection (a), including the frequency of application of remedies specified in section 1822(c)(5)(B) of the Social Security Act (as added by such subsection), on access to, and quality of, care furnished by hospice programs under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.).

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

H.R. 5821 the *Helping Our Senior Population in Comfort Environments (HOSPICE) Act,* as amended and ordered reported by the Committee on Ways and Means on February 12, 2020, amends Title XVIII of the Social Security Act to provide additional oversight and transparency of Medicare hospice providers, which deliver care to patients nearing the end of life. H.R. 5821 was introduced by Representatives Jimmy Panetta (D–CA–) and Tom Reed (R–NY), on February 10, 2020.

B. BACKGROUND AND NEED FOR LEGISLATION

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) released two reports in July 2019 that identified significant deficiencies in the quality of care delivered to Medicare hospice enrollees.[1] [2] According to the OIG studies, 87 percent of hospices had at least one care deficiency between 2012 and 2016. Twenty percent (903 out of 4,563 hospices surveyed) had at least one serious deficiency, meaning the health and safety of a beneficiary were in jeopardy or the hospice was limited in its capacity to deliver adequate care. The OIG issued a series of recommendations for the improvement of quality in hospice care, many of which are addressed through H.R. 5821.

Consistent with the OIG recommendations, H.R. 5821 provides the HHS Secretary (the Secretary) with additional tools, which align those that already exist for Medicare-certified skilled nursing facilities and home health agencies, to oversee the hospice program and provide support to help poor-performing hospices improve. The legislation requires the Secretary to develop a series of intermediate remedies—including corrective action plans, suspension of payment, and civil monetary penalties (CMPs)—in cases where the patient's health is at risk. Some penalties paid under these addi-

[1] *Hospice Deficiencies Pose Risks to Medicare Beneficiaries*, HHS OFFICE OF INSPECTOR GENERAL (July 3, 2019), https://oig.hhs.gov/oei/reports/oei-02-17-00020.asp?utm_source=mmpage&utm_medium=web&utm_campaign=OEI-02-17-00020.

[2] *Safeguards Must Be Strengthened to Protect Medicare Hospice Beneficiaries From Harm*, HHS OFFICE OF INSPECTOR GENERAL (July 3, 2019), https://oig.hhs.gov/oei/reports/oei-02-17-00021.asp?utm_source=mmpage&utm_medium=web&utm_campaign=OEI-02-17-00021.

tional oversight standards may be reinvested back into the hospice program for education of poor-performing providers. The HOSPICE Act additionally requires state and federal surveyors to receive comprehensive training to ensure consistent enforcement of the Centers for Medicare & Medicaid Services (CMS) surveyor guidance.

The HOSPICE Act also builds on improvements made in the bipartisan Improving Medicare Post-Acute Care Transformation Act of 2014 [3] by further increasing the frequency of surveys of hospices from once every three years (as required under the IMPACT Act) to once every two years. The bill requires accreditation organizations who survey hospices to submit their survey results to the Secretary and for CMS to publicly display that information in an easily understandable format on the agency's website.

H.R. 5821 additionally creates a "Special Focus Facility" program that requires the Secretary to monitor and more frequently survey poor-performing hospices, and the legislation further requires states to maintain a toll-free hotline for hospice patients and their families to report abuse and neglect, similar to the one currently available for Medicare beneficiaries using home health services. Finally, the bill increases the penalty, from two percentage points to four, for hospices that do not report quality data to the Secretary.

C. LEGISLATIVE HISTORY

Background

H.R. 5821 was introduced on February 10, 2020, and was referred to the Committee on Ways and Means and additionally to the Committee on Energy and Commerce.

Committee hearings

On November 13, 2019, the Committee on Ways and Mean held a hearing entitled, "Caring for Aging Americans." Among the witnesses was Edo Banach, JD, President & Chief Executive Officer of the National Hospice and Palliative Care Organization, who discussed the challenges in the Medicare hospice program, including the recent OIG report and the need for increased oversight of the hospice program to protect patients.

Committee action

The Committee on Ways and Means marked up H.R. 5821, the HOSPICE Act, on February 12, 2020, and ordered the bill, as amended, favorably reported by a voice vote (with a quorum being present).

II. EXPLANATION OF THE BILL

A. THE *HOSPICE ACT*

Current Law

The Medicare hospice benefit provides coverage for certain services for Medicare beneficiaries with a life expectancy of six months or less. The Medicare benefit covers a broad range of services, including skilled nursing care; physician, home health aide and

[3] Pub. L. No. 113–185.

homemaker services; and patient as well as family bereavement counseling. Services are provided primarily in the patient's home but may also be provided in institutional settings, such as long-term care facilities.

Hospice services must be provided by a Medicare-certified hospice agency. A certified hospice agency must be either a public agency or private organization (or a subdivision of either) that is primarily engaged in providing covered hospice services and must make services available on a 24-hour basis. To obtain and maintain federal certification, hospice agencies must comply with federal regulatory requirements known as the Conditions of Participation (CoPs). Medicare CoPs are distinct from any state operational licensing requirements and incorporate specific and general requirements set forth in section 1861(dd) of the Social Security Act (SSA). The CoPs include a broad array of requirements, such as the scope of required services, patient rights (e.g., freedom from abuse), and the organizational environment and structure of the agency—including, but not limited to, staff qualifications and the processes of clinical records management and/or infection control.

There are two ways a hospice agency may be certified for compliance of the CoPs. First, hospice agencies may choose to use a private accrediting organization (AO) that is approved by the Secretary. Second, if a hospice agency chooses not to be accredited by an AO for certification, this agency is certified for compliance by its respective local or state survey agency (SA), in coordination with the Secretary. AOs and SAs ensure the compliance of hospice agencies by, among other actions, responding to any complaints made by beneficiaries, the public, or representatives within the agency, and by performing surveys, which generally are unannounced visits by a professional or a team of professionals, known as a survey team, to verify compliance with all regulatory requirements (i.e., the CoPs). Survey teams can be deployed to conduct:

1. An initial Medicare certification survey to determine compliance of all CoPs for a prospective agency,
2. Complaint investigations to assess the compliance of specific CoPs, and/or
3. A standard survey, which occurs periodically to comprehensively assess the compliance of all CoPs.

Surveys performed by SAs are subject to federal oversight, which can include the auditing by federal surveyors.

Before the IMPACT Act, there was no statutory-required frequency for which standard surveys of hospice agencies were required to be completed. Additionally, aside from funding made through general discretionary appropriations, there was no mandatory spending specifically provided for surveying hospice agencies. The IMPACT Act of 2014 amended Section 1861 of the SSA to require that all hospice agencies be surveyed by an SA or AO at least once every three years. The requirement started six months after the October 6, 2014, enactment of the IMPACT Act of 2014 and is set to end after Fiscal Year (FY) 2025 (September 30, 2025). For purposes of performing standard surveys, the IMPACT Act of 2014 provided funding by directing transfer from the Federal Hospital Insurance (HI) Trust Fund to the CMS Program Management Account, in the amount of $25 million for each of FY 2015–2017 and $45 million for each of FY 2018–2025.

Although there currently are no statutory requirements for the composition of survey teams, CMS provides guidance to all surveyors as to the correct protocol for conducting a standard survey as it relates to the relevant areas and items that must be inspected or reviewed for each CoP. In addition to this general guidance, CMS also details specific requirements that are directed only at SAs. For example, CMS requires SAs to use the CMS document entitled "Principles of Documentation for the Statement of Deficiencies" (referred to as Form CMS 2567) to document and report CoP deficiencies cited during a survey. AOs have greater discretion, although their process could be contingent upon approval of the organization by the Secretary as to how deficiencies are documented and reported. Regardless of the manner in which an AO constructs survey documentation, Section 1865 of the SSA prohibits the Secretary from disclosing the "survey or information related to the survey," except to the extent such survey and information is related to an enforcement action taken by the Secretary.

To enforce compliance of federal requirements, the Secretary has the authority to terminate the certification of a hospice agency, which would remove the agency from the Medicare program. The Secretary is not statutorily authorized to impose certain remedies that are authorized for deficiencies found during the surveys of other Medicare-certified organizations. For example, the Secretary is authorized to impose fines (or CMPs), for deficiencies found during the surveys of skilled nursing facilities (SNFs) and Medicare home health agencies. Currently, however, the Secretary is not authorized by law to impose CMPs to hospice agencies for noncompliance.

Under Section 1814 of the SSA, the Secretary is required to assess a financial penalty against hospice agencies that do not report specified quality data to the Secretary. Currently, hospice agencies that do not report quality data have their Medicare hospice payments reduced by two percent.

Lastly, under Section 1864 of the SSA, SAs, in an agreement with the Secretary, must maintain toll-free hotlines to collect information pertaining to Medicare home health agencies. Specifically, SAs must maintain hotlines that (1) collect, maintain, and continually update information on home health agencies, including significant deficiencies found with respect to a survey conducted by an AO and any sanctions imposed, and (2) receive complaints and answer questions with respect to home health agencies. SAs are also required to maintain a unit for investigating complaints that has enforcement authority and access to survey reports of AOs and related medical records (with consent of the individual or his or her legal representative). Each investigative unit's enforcement authority is limited to remedies authorized by law, although states may develop remedial actions of their own.

Reasons for Change

Given the OIG's reports of patient safety concerns across many hospices in the Medicare hospice program and the lack of intermediary oversight and enforcement tools at the Secretary's disposal, the Committee believes it is necessary to improve hospice quality and ensure greater parity across Medicare's post-acute and end-of-life settings of care. More specifically, the provisions in H.R.

5821 require the Secretary to implement a number of changes to the hospice program to align it with both the SNF and home health settings and improve the quality of care delivered to Medicare beneficiaries receiving hospice services. Thus, the Committee anticipates CMS will implement these statutory changes in a manner consistent with the programs that already exist in other Medicare settings of care.

In developing this policy, consideration was given to the inclusion of CMPs as an enforcement mechanism in the hospice program, given concerns expressed by industry stakeholders about the potential of such penalties to be punitive. Ultimately, the policy recognizes CMPs are vital to ensuring the Secretary will have at his or her disposal all of the same similar mechanisms available in other settings of care to ensure patient safety. The Secretary is encouraged to deploy these new tools in a manner consistent with CMPs used in other settings of care and in proportion to the severity of the deficiency so that such penalties result in improved care for hospice patients.

The bill also requires the Secretary to establish a "Special Focus Program" for hospice agencies that the Secretary identifies as having substantially failed to meet certification requirements, similar to the Special Focus Program that current exists for SNFs. The Committee encourages CMS to produce clear guidance for the program, including defining "substantially failed to meet," to ensure hospices, SAs, and AOs have a clear understanding of the criteria the Secretary intends to apply for entering and exiting the program.

The policy additionally requires the Secretary to provide "comprehensive training" to all state and federal surveyors of hospice agencies. The purpose of this provision is to ensure greater uniformity across SAs and AOs as well as to increase understanding of the unique aspects of the delivery of hospice care. The comprehensive training would be required to include training with respect to hospice written plans of care. The Committee encourages CMS to include consideration for a provider's electronic medical record in this plan-of-care training. To ensure uniformity across hospice surveyors, the Committee further encourages CMS to include training tailored specific to hospice survey and certification techniques, as the patient population has unique needs from other settings of care. Such training could also include ways to better educate hospice providers on emergency preparedness, including, but not limited to, communication and risk assessment.

Explanation of Provisions

Section 1. Short Title.

The short title for this bill is the Helping Our Senior Population in Comfort Environments (HOSPICE) Act.

Section 2. Establishing Hospice Program Survey and Enforcement Procedures Under the Medicare Program.

(a) Survey and Enforcement Procedures

Subsection (a)(1) establishes a new section 1822 in Part A of Title XVIII of the SSA. The following explanation of provisions refers to the new section 1822 as created by H.R. 5821.

Survey Frequency and Funding

New paragraph 1822(a)(1) requires a SA or AO to perform a standard survey of each Medicare hospice agency at a frequency of no less than once every three years, until the end of FY2021. Beginning FY2022, a SA or AO would be required to perform a standard survey of each Medicare hospice agency at a frequency of no less than once every two years.

New paragraph 1822(a)(2) requires that each state and accreditation agency submit survey and certification information to the Secretary. Such information shall be publicly disclosed in an easy-to-understand format on CMS's public website in a timely manner.

New paragraph 1822(a)(3) requires each state and the Secretary to implement programs that measure and reduce the inconsistency of the application of surveys across different surveyors.

New paragraph 1822(a)(4) mandates that any standard survey conducted by more than one surveyor shall be conducted by a "multidisciplinary team of professionals," with at least one registered nurse serving as a member of the survey team. Additionally, states would be prohibited from surveying a hospice agency with a survey team that includes an individual who is serving, or has served within the previous two years, as a staff member of or a consultant to the agency. This prohibition applies to any person who "has personal or familial financial interest" in the hospice agency being surveyed. The paragraph also specifies that no later than October 1, 2021, the Secretary must provide "comprehensive training" to all state and federal surveyors of hospice agencies.

New paragraph 1822(a)(5) provides funding, in the same manner (from the HI Trust Fund), and in addition to the funding provided by the IMPACT Act of 2014, to the CMS Program Management Account in the amount of $10 million per FY, beginning FY 2022. The funds would available for carrying out standard surveys and would remain available until expended.

Special Focus Program

New subsection 1822(b) requires the Secretary to create a Special Focus Program for poor-performing hospices, who will be surveyed not less frequently than once every six months.

Enforcement

New subsection 1822(c) establishes two processes for the enforcement of compliance when deficiencies are discovered during a standard survey or otherwise. The main determinant of which process would be used would be whether any discovered deficiencies immediately jeopardize the health and safety of the individuals receiving hospice care (which is referred to as the presence of immediate jeopardy (IJ)).

1. If the presence of an IJ exists, the Secretary would be required to take immediate action to either remove the IJ and correct the deficiencies through the remedy of temporary management or terminate the certification of the program and may also impose aforementioned remedies.

2. If the presence of IJ does not exist, the Secretary would be permitted, for a period of time that is not to exceed six months, to impose aforementioned remedies in lieu of terminating the certification of the agency. If after the period of time the agency is still

out of compliance with federal requirements, the Secretary would be required to terminate the agency's certification.

In either situation, the Secretary would be able to continue Medicare payments to a hospice agency found out of compliance for a period up to six months, if:

1. The SA finds that it is more appropriate to take alternative action to assure compliance of the program with such requirements than to terminate the agency's certification;

2. The agency has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action (under the guidelines established by the Secretary); and

3. The agency agrees to repay to the federal government and Medicare payments received during such period if the corrective action is not taken in accordance with the approved plan and timetable.

If the Secretary determines a hospice agency is currently in compliance with CoPs but was previously noncompliant, the Secretary would be permitted to assess the agency a CMP for days in which the Secretary finds the agency was not in compliance with the CoPs.

Subsection (c) also requires that the Secretary, no later than the beginning of FY 2022, develop and implement remedies that would be in addition to current federal and state sanctions and would not be construed as limiting other existing remedies. Specified remedies are to include:

1. CMPs, not to exceed $10,000 for each day of noncompliance with the CoPs, to be applied using the processes set forth under Section 1128A of the SSA, which provides general authorities to the Secretary, and sets parameters, for the imposition of CMPs.

2. The appointment of temporary management to oversee the operation of a hospice agency. The temporary management would remain until the Secretary has determined that the agency has the management capability to ensure continued compliance of certification requirements.

3. The suspension of all or part of Medicare payments, which would terminate when the Secretary finds that the program is in "substantial compliance" of all certification requirements.

No later than the beginning of FY 2022, the Secretary would be required to implement specific procedures for the conditions under which the established remedies would be applied. Such procedures would include the amount of any CMP and the severity of each remedy. The procedures would be required to be designed so as to minimize the time between identification of deficiencies and the imposition of remedies, and to allow for incrementally more severe fines for repeated or uncorrected deficiencies. Additionally, the procedures would be required to include a process for appealing determinations relating to the imposition of the established remedies.

The Secretary would be able collect a portion of CMPs collected from noncompliant hospice agencies and use those funds to support activities that benefit individuals receiving hospice care, including education and training programs to ensure compliance with Medicare's hospice CoPs.

Additional Provisions

In addition to creating a new section 1822 in Part A of Title XVIII of the SSA, subsection (a) of the bill also amends SSA Section 1865 to allow the Secretary to disclose an AO's hospice survey report, or information related to the survey, regardless of whether or not the disclosure relates to an enforcement action taken by the Secretary.

Subsection (a) also amends Section 1864 of the SSA to include hospice agencies among the providers for which State or local agencies must maintain a toll-free hotline for the reporting of deficiencies and complaints, in addition to a unit for processing such complaints. This would be effective one year after the enactment of the proposed law.

(b) Increasing Payment Reductions for Failure to Meet Quality Data Reporting Requirements

Subsection (b) increases the penalty for hospices not reporting quality data to the Secretary from two to four percentage points, beginning in FY 2021.

(c) Report

Subsection (c) requires the GAO to submit to the House Committee on Ways and Means and the Senate Finance Committee, no later than 36 months from enactment, a report that contains an analysis of (1) the effects of the new requirements under the new SSA Section 1822(a), (2) the frequency of application of remedies specified by the proposed law, and (3) access to, and quality of, hospice care provided by Medicare-certified hospice agencies.

Effective Date

Section 2: Survey frequency updated to not less frequently than once every 24 months, effective October 1, 2021.

Requirement that each national accreditation body complete Form 2567, effective October 1, 2021.

Requirement that the Secretary publish survey information on the CMS website, effective October 1, 2022.

Requirement that survey teams of more than one be conducted by a multidisciplinary team of professionals, effective October 1, 2021.

Requirement that surveyors not have conflicts of interest, effective October 1, 2021.

Requirement that the Secretary provide surveyor training, no later than October 1, 2021.

Funding provided each FY, beginning with FY 2022.

Requirement that the Secretary develop a Special Focus Program, effective on the date of enactment.

Requirement that the Secretary develop enforcement penalties, no later than October 1, 2021.

Availability of accreditation surveys, effective on the date of enactment.

Inclusion of hospices in each State's toll-free hotline, effective one year after the date of enactment.

Increase in quality reporting payment reduction, starting on FY 2023.

GAO report to Congress, no later than October 1, 2024.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means in its consideration of H.R. 5821, the HOSPICE Act, on February 12, 2020.

The Chairman's amendment in the nature of a substitute was adopted by a voice vote (with a quorum being present).

The bill, H.R. 5821 as amended, was ordered favorably reported by voice vote (with a quorum being present).

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the bill, H.R. 5821, as reported. The Committee agrees with the estimate prepared by the Congressional Budget Office (CBO), which is included below.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new or increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 1, 2020.

Hon. RICHARD NEAL,
Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 5821, the Helping Our Senior Population in Comfort Environments Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Sarah Sajewski, who can be reached at 226–9010.

Sincerely,

PHILLIP L. SWAGEL,
Director.

Enclosure.

H.R. 5821, Helping Our Senior Population in Comfort Environments Act
As ordered reported by the House Committee on Ways and Means on February 12, 2020

By Fiscal Year, Millions of Dollars	2021	2021-2025	2021-2030
Direct Spending (Outlays)	0	-26	-136
Revenues	0	22	52
Increase or Decrease (-) in the Deficit	0	-48	-188
Spending Subject to Appropriation (Outlays)	0	0	0

Statutory pay-as-you-go procedures apply?	Yes	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2031?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

H.R. 5821 would require hospice programs participating in Medicare to undergo periodic surveys to ensure they comply with federal standards. Under the bill, the Secretary of Health and Human Services (HHS) could collect civil monetary penalties from programs that fail to meet those standards. Under the bill, hospice providers that fail to report certain data to the Centers for Medicare & Medicaid Services (CMS) would be subject to a reduction in federal payments that is larger than the reduction applied under current law.

Provisions affecting direct spending: Overall, CBO estimates that H.R. 5821 would reduce net direct spending by $136 million over the 2021 2030 period (see Table 1).

Since 2014, hospice programs that do not report certain quality data to CMS have been subject to a 2 percent reduction in their annual payments. Using information on the share of hospice programs that do not now report such data, CBO estimates that over the 2021–2030 period, programs accounting for about 15 percent of Medicare's payments to hospices will be subject to the current-law reduction. Starting in 2023, H.R. 5821 would increase the reduction to 4 percent. CBO estimates that under the bill, the number of hospices that do not report would decline, and 10 percent of Medicare's payments to hospices would be subject to the 4 percent reduction. CBO estimates that the provision would decrease direct spending by $277million over the 2021–2030 period.

Beginning in 2022, the bill would provide for a transfer of $10 million annually from the Hospital Insurance (HI) Trust Fund to CMS to fund surveys of hospice programs. The funds would cover the cost of training surveyors and reviewing and publishing survey results. CBO estimates that CMS would receive $90 million in transfers from the HI trust fund over the 2021–2030 period and that it would spend those amounts over the period to implement the new requirements.

The bill would also give the Secretary authority to assess penalties on hospice providers for failing to comply with certain Medicare requirements. The Secretary would then be able to spend amounts that are collected. CBO estimates that the new authority would increase federal spending by $51 million over the 2021 2030

period. The revenues collected under this provision are discussed below.

Provision affecting direct spending and revenues: Under current law, the Secretary of HHS cannot impose civil monetary penalties when a hospice provider fails to comply with certain Medicare requirements. H.R. 5821 would give the Secretary authority to assess penalties of up to $10,000 for each day that a provider is found not to be in compliance. Under the bill, the Secretary of HHS could then spend revenues collected in this manner on efforts to improve the Medicare program. Using information on the number of hospice programs that have received termination notices from CMS, CBO estimates that under this provision, the federal government would collect $52million in revenues over the 2021–2030 period.

Uncertainty: The key source of uncertainty in this estimate is accurately assessing the number of hospices that do not report quality data to CMS. Hospice providers vary greatly in their size and business model, and it is difficult to anticipate their decision making about whether to report data under the increased payment reduction. Savings under the bill could be larger or smaller than CBO estimates depending on the number of hospice providers that report data.

The CBO staff contact for this estimate is Sarah Sajewski. The estimate was reviewed by Paul Masi, Unit Chief for Health Systems and Medicare, and Leo Lex, Deputy Director of Budget Analysis.

TABLE 1.—ESTIMATED BUDGETARY EFFECTS OF H.R. 5821

	By fiscal year, millions of dollars—											
	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2021–2025	2021–2030
Net Increase or Decrease (−) in Direct Spending Outlays												
Funding for Hospice Surveys [a]	0	10	10	10	10	10	10	10	10	10	40	90
Increasing the Reduction in Payments for Hospices Not Reporting Quality Data [a]	0	0	−27	−29	−31	−33	−35	−38	−40	−44	−87	−277
Spending From Authority to Apply a Civil Monetary Penalty: [b]												
Budget Authority	0	5	5	6	6	6	6	6	6	6	22	52
Outlays	0	4	5	6	6	6	6	6	6	6	21	51
Total Changes in Direct Spending:												
Estimated Budget Authority	0	15	−12	−13	−15	−17	−19	−22	−24	−28	−25	−135
Estimated Direct Spending	0	14	−12	−13	−15	−17	−19	−22	−24	−28	−26	−136
Increases in Revenues												
Revenues From Authority to Apply a Civil Monetary Penalty [b]	0	5	5	6	6	6	6	6	6	6	22	52
Net Increase or Decrease (−) in the Deficit From Changes in Direct Spending and Revenues												
Effect on the Deficit	0	9	−17	−19	−21	−23	−25	−28	−30	−34	−48	−188

Components may not sum to totals because of rounding; estimates are relative to CBO's March 2020 Baseline.
a. Budget authority equals outlays.
b. Proposal would increase both direct spending and revenues, which are shown separately.

V. Other Matters To Be Discussed Under the Rules of the House

A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

With respect to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the Committee made findings and recommendations that are reflected in this report.

B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill contains no measure that authorizes funding, so no statement of general performance goals and objectives for which any measure authorizes funding is required.

C. INFORMATION RELATING TO UNFUNDED MANDATES

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104–4).

The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

D. CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

E. DUPLICATION OF FEDERAL PROGRAMS

In compliance with clause 3(c)(5) of rule XIII of the Rules of the House of Representatives, the Committee states that no provision of the bill establishes or reauthorizes:

(1) a program of the Federal Government known to be duplicative of another Federal program;

(2) a program included in any report to Congress pursuant to section 21 of Public Law 111–139; or

(3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant section 6104 of title 31, United States Code.

F. HEARINGS

In compliance with Sec.103(i) of H. Res. 6 (116th Congress)

(1) the following hearing was used to develop or consider H.R. 5821:

On November 13, 2019, the Committee on Ways and Means held a full-committee hearing entitled, “Caring for Aging Americans.”

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e)(1)(B) of rule XIII of the Rules of the House of Representatives, changes in existing law proposed by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * * * *

PART A—HOSPITAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * * * *

CONDITIONS OF AND LIMITATIONS ON PAYMENT FOR SERVICES

Requirement of Requests and Certifications

SEC. 1814. (a) Except as provided in subsections (d) and (g) and in section 1876, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1866 and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service;

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner, a clinical nurse specialist, or a physician assistant (as those terms are defined in section 1861(aa)(5)) who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician,, or, in the case of services described in subparagraph (C), a physician enrolled under section 1866(j), certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that—

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the psychiatric treatment of an individual; and (i) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically re-

quired and such services are or were necessary for such purposes;

(B) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (9) of section 1861(e)) prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving such inpatient hospital services;

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1861(m)(7)) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; such services are or were furnished while the individual was under the care of a physician, and, in the case of a certification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician himself or herself, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg)) as authorized by State law, or a physician assistant (as defined in section 1861(aa)(5)) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth, subject to the requirements in section 1834(m), and other than with respect to encounters that are incident to services involved) with the individual within a reasonable timeframe as determined by the Secretary; or

(D) in the case of inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(3) with respect to inpatient hospital services (other than inpatient psychiatric hospital services) which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose, except that (A) such certification shall be furnished only in such cases, with such frequency, and accompanied by such supporting material, appropriate to the cases involved, as may be provided by regulations, and (B) the first such certification required in accordance with clause (A) shall be furnished no later than the 20th day of such period;

(4) in the case of inpatient psychiatric hospital services, the services are those which the records of the hospital indicate were furnished to the individual during periods when he was receiving (A) intensive treatment services, (B) admission and related services necessary for a diagnostic study, or (C) equivalent services;

(5) with respect to inpatient hospital services furnished such individual after the 20th day of a continuous period of such services, there was not in effect, at the time of admission of such individual to the hospital, a decision under section 1866(d) (based on a finding that utilization review of long-stay cases is not being made in such hospital);

(6) with respect to inpatient hospital services or post-hospital extended care services furnished such individual during a continuous period, a finding has not been made (by the physician members of the committee or group, as described in section 1861(k)(4), including any finding made in the course of a sample or other review of admissions to the institution) pursuant to the system of utilization review that further inpatient hospital services or further post-hospital extended care services, as the case may be, are not medically necessary; except that, if such a finding has been made, payment may be made for such services furnished before the 4th day after the day on which the hospital or skilled nursing facility, as the case may be, received notice of such finding;

(7) in the case of hospice care provided an individual—

(A)(i) in the first 90-day period—

(I) the individual's attending physician (as defined in section 1861(dd)(3)(B)) (which for purposes of this subparagraph does not include a nurse practitioner or a physician assistant), and

(II) the medical director (or physician member of the interdisciplinary group described in section 1861(dd)(2)(B)) of the hospice program providing (or arranging for) the care,

each certify in writing at the beginning of the period, that the individual is terminally ill (as defined in section 1861(dd)(3)(A)) based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness, and

(ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at

the beginning of the period that the individual is terminally ill based on such clinical judgment;

(B) a written plan for providing hospice care with respect to such individual has been established (before such care is provided by, or under arrangements made by, that hospice program) and is periodically reviewed by the individual's attending physician and by the medical director (and the interdisciplinary group described in section 1861(dd)(2)(B)) of the hospice program;

(C) such care is being or was provided pursuant to such plan of care;

(D) on and after January 1, 2011 (and, in the case of clause (ii), before the date of enactment of subparagraph (E))—

(i) a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification under subparagraph (A)(ii) and attests that such visit took place (in accordance with procedures established by the Secretary); and

(ii) in the case of hospice care provided an individual for more than 180 days by a hospice program for which the number of such cases for such program comprises more than a percent (specified by the Secretary) of the total number of such cases for all programs under this title, the hospice care provided to such individual is medically reviewed (in accordance with procedures established by the Secretary); and

(E) on and after the date of enactment of this subparagraph, in the case of hospice care provided an individual for more than 180 days by a hospice program for which the number of such cases for such program comprises more than a percent (specified by the Secretary) of the total number of all cases of individuals provided hospice care by the program under this title, the hospice care provided to such individual is medically reviewed (in accordance with procedures established by the Secretary); and

(8) in the case of inpatient critical access hospital services, a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the critical access hospital.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician, nurse practitioner, clinical nurse specialist, or physician assistant (as the case may be) makes certification of the kind provided in subparagraph (A), (B), (C), or (D) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effec-

tive no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of documentation for physician certification and recertification made under paragraph (2) on or after January 1, 2019, and made with respect to home health services furnished by a home health agency, in addition to using documentation in the medical record of the physician who so certifies or the medical record of the acute or post-acute care facility (in the case that home health services were furnished to an individual who was directly admitted to the home health agency from such a facility), the Secretary may use documentation in the medical record of the home health agency as supporting material, as appropriate to the case involved. For purposes of paragraph (2)(C), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be "confined to his home". Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.

Amount Paid to Providers

(b) The amount paid to any provider of services (other than a hospice program providing hospice care, other than a critical access hospital providing inpatient critical access hospital services, and other than a home health agency with respect to durable medical equipment) with respect to services for which payment may be made under this part shall, subject to the provisions of sections 1813, 1886, and 1895, be—

(1) except as provided in paragraph (3), the lesser of (A) the reasonable cost of such services, as determined under section 1861(v) and as further limited by section 1881(b)(2)(B), or (B) the customary charges with respect to such services;

(2) if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this paragraph), free of charge or at nominal charges to the public, the amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the determination of such reasonable cost which the Secretary finds will provide fair compensation to such provider for such services; or

(3) if some or all of the hospitals in a State have been reimbursed for services (for which payment may be made under this part) pursuant to a reimbursement system approved as a demonstration project under section 402 of the Social Security Amendments of 1967 or section 222 of the Social Security Amendments of 1972, if the rate of increase in such hospitals in their costs per hospital inpatient admission of individuals entitled to benefits under this part over the duration of such project was equal to or less than such rate of increase for admissions of such individuals with respect to all hospitals in the United States during such period, and if either the State has legislative authority to operate such system and the State elects to have reimbursement to such hospitals made in accordance with this paragraph or the system is operated through a voluntary agreement of hospitals and such hospitals elect to have reimbursement to those hospitals made in accordance with this paragraph, then, subject to section 1886(d)(3)(B)(ix)(III), the Secretary may provide for continuation of reimbursement to such hospitals under such system until the Secretary determines that—

(A) a third-party payor reimburses such a hospital on a basis other than under such system, or

(B) the aggregate rate of increase from January 1, 1981, to the most recent date for which annual data are available in such hospitals in costs per hospital inpatient admission of individuals entitled to benefits under this part is greater than such rate of increase for admissions of such individuals with respect to all hospitals in the United States for such period.

In the case of any State which has had such a demonstration project reimbursement system in continuous operation since July 1, 1977, the Secretary shall provide under paragraph (3) for continuation of reimbursement to hospitals in the State under such system until the first day of the 37th month beginning after the date the Secretary determines and notifies the Governor of the State that either of the conditions described in subparagraph (A) or (B) of such paragraph has occurred. If, by the end of such 36-month period, the Secretary determines, based on evidence submitted by the Governor of the State, that neither of the conditions described in subparagraph (A) or (B) of paragraph (3) continues to apply, the Secretary shall continue without interruption payment to hospitals in

the State under the State's system. If, by the end of such 36-month period, the Secretary determines, based on such evidence, that either of the conditions described in subparagraph (A) or (B) of such paragraph continues to apply, the Secretary shall (i) collect any net excess reimbursement to hospitals in the State during such 36-month period (basing such net excess reimbursement on the net difference, if any, in the rate of increase in costs per hospital inpatient admission under the State system compared to the rate of increase in such costs with respect to all hospitals in the United States over the 36-month period, as measured by including the cumulative savings under the State system based on the difference in the rate of increase in costs per hospital inpatient admission under the State system as compared to the rate of increase in such costs with respect to all hospitals in the United States between January 1, 1981, and the date of the Secretary's initial notice), and (ii) provide a reasonable period, not to exceed 2 years, for transition from the State system to the national payment system. For purposes of applying paragraph (3), there shall be taken into account incentive payments, and payment adjustments under subsection (b)(3)(B)(ix) or (n) of section 1886.

No Payments to Federal Providers of Services

(c) Subject to section 1880, no payment may be made under this part (except under subsection (d) or subsection (h)) to any Federal provider of services, except a provider of services which the Secretary determines is providing services to the public generally as a community institution or agency; and no such payment may be made to any provider of services for any item or service which such provider is obligated by a law of, or a contract with, the United States to render at public expense.

Payments for Emergency Hospital Services

(d)(1) Payments shall also be made to any hospital for inpatient hospital services furnished in a calendar year, by the hospital or under arrangements (as defined in section 1861(w)) with it, to an individual entitled to hospital insurance benefits under section 226 even though such hospital does not have an agreement in effect under this title if (A) such services were emergency services, (B) the Secretary would be required to make such payment if the hospital had such an agreement in effect and otherwise met the conditions of payment hereunder, and (C) such hospital has elected to claim payments for all such inpatient emergency services and for the emergency outpatient services referred to in section 1835(b) furnished during such year. Such payments shall be made only in the amounts provided under subsection (b) and then only if such hospital agrees to comply, with respect to the emergency services provided, with the provisions of section 1866(a).

(2) Payment may be made on the basis of an itemized bill to an individual entitled to hospital insurance benefits under section 226 for services described in paragraph (1) which are emergency services if (A) payment cannot be made under paragraph (1) solely because the hospital does not elect to claim such payment, and (B) such individual files application (submitted within such time and in such form and manner and by such person, and containing and

supported by such information as the Secretary shall by regulations prescribe) for reimbursement.

(3) The amounts payable under the preceding paragraph with respect to services described therein shall, subject to the provisions of section 1813, be equal to 60 percent of the hospital's reasonable charges for routine services furnished in the accommodations occupied by the individual or in semiprivate accommodations (as defined in section 1861(v)(4)), whichever is less, plus 80 percent of the hospital's reasonable charges for ancillary services. If separate charges for routine and ancillary services are not made by the hospital, reimbursement may be based on two-thirds of the hospital's reasonable charges for the services received but not to exceed the charges which would have been made if the patient had occupied semiprivate accommodations. For purposes of the preceding provisions of this paragraph, the term "routine services" shall mean the regular room, dietary, and nursing services, minor medical and surgical supplies and the use of equipment and facilities for which a separate charge is not customarily made; the term "ancillary services" shall mean those special services for which charges are customarily made in addition to routine services.

Payment for Inpatient Hospital Services Prior to Notification of Noneligibility

(e) Notwithstanding that an individual is not entitled to have payment made under this part for inpatient hospital services furnished by any hospital, payment shall be made to such hospital (unless it elects not to receive such payment or, if payment has already been made by or on behalf of such individual, fails to refund such payment within the time specified by the Secretary) for such services which are furnished to the individual prior to notification to such hospital from the Secretary of his lack of entitlement, if such payments are precluded only by reason of section 1812 and if such hospital complies with the requirements of and regulations under this title with respect to such payments, has acted in good faith and without knowledge of such lack of entitlement, and has acted reasonably in assuming entitlement existed. Payment under the preceding sentence may not be made for services furnished an individual pursuant to any admission after the 6th elapsed day (not including as an elapsed day Saturday, Sunday, or a legal holiday) after the day on which such admission occurred.

Payment for Certain Inpatient Hospital Services Furnished Outside the United States

(f)(1) Payment shall be made for inpatient hospital services furnished to an individual entitled to hospital insurance benefits under section 226 by a hospital located outside the United States, or under arrangements (as defined in section 1861(w)) with it, if—

(A) such individual is a resident of the United States, and

(B) such hospital was closer to, or substantially more accessible from, the residence of such individual than the nearest hospital within the United States which was adequately equipped to deal with, and was available for the treatment of, such individual's illness or injury.

(2) Payment may also be made for emergency inpatient hospital services furnished to an individual entitled to hospital insurance benefits under section 226 by a hospital located outside the United States if—

(A) such individual was physically present—

(i) in a place within the United States; or

(ii) at a place within Canada while traveling without unreasonable delay by the most direct route (as determined by the Secretary) between Alaska and another State;

at the time the emergency which necessitated such inpatient hospital services occurred, and

(B) such hospital was closer to, or substantially more accessible from, such place than the nearest hospital within the United States which was adequately equipped to deal with, and was available for the treatment of, such individual's illness or injury.

(3) Payment shall be made in the amount provided under subsection (b) to any hospital for the inpatient hospital services described in paragraph (1) or (2) furnished to an individual by the hospital or under arrangements (as defined in section 1861(w)) with it if (A) the Secretary would be required to make such payment if the hospital had an agreement in effect under this title and otherwise met the conditions of payment hereunder, (B) such hospital elects to claim such payment, and (C) such hospital agrees to comply, with respect to such services, with the provisions of section 1866(a).

(4) Payment for the inpatient hospital services described in paragraph (1) or (2) furnished to an individual entitled to hospital insurance benefits under section 226 may be made on the basis of an itemized bill to such individual if (A) payment for such services cannot be made under paragraph (3) solely because the hospital does not elect to claim such payment, and (B) such individual files application (submitted within such time and in such form and manner and by such person, and continuing and supported by such information as the Secretary shall by regulations prescribe) for reimbursement. The amount payable with respect to such services shall, subject to the provisions of section 1813, be equal to the amount which would be payable under subsection (d)(3).

Payment for Services of a Physician Rendered in a Teaching Hospital

(g) For purposes of services for which the reasonable cost thereof is determined under section 1861(v)(1)(D) (or would be if section 1886 did not apply), payment under this part shall be made to such fund as may be designated by the organized medical staff of the hospital in which such services were furnished or, if such services were furnished in such hospital by the faculty of a medical school, to such fund as may be designated by such faculty, but only if—

(1) such hospital has an agreement with the Secretary under section 1866, and

(2) the Secretary has received written assurances that (A) such payment will be used by such fund solely for the improvement of care of hospital patients or for educational or charitable purposes and (B) the individuals who were furnished such services or any other persons will not be charged for such

services (or if charged, provision will be made for return of any moneys incorrectly collected).

Payment for Certain Hospital Services Provided in Department of Veterans Affairs Hospitals

(h)(1) Payments shall also be made to any hospital operated by the Department of Veterans Affairs for inpatient hospital services furnished in a calendar year by the hospital, or under arrangements (as defined in section 1861(w)) with it, to an individual entitled to hospital benefits under section 226 even though the hospital is a Federal provider of services if (A) the individual was not entitled to have the services furnished to him free of charge by the hospital, (B) the individual was admitted to the hospital in the reasonable belief on the part of the admitting authorities that the individual was a person who was entitled to have the services furnished to him free of charge, (C) the authorities of the hospital, in admitting the individual, and the individual, acted in good faith, and (D) the services were furnished during a period ending with the close of the day on which the authorities operating the hospital first became aware of the fact that the individual was not entitled to have the services furnished to him by the hospital free of charge, or (if later) ending with the first day on which it was medically feasible to remove the individual from the hospital by discharging him therefrom or transferring him to a hospital which has in effect an agreement under this title.

(2) Payment for services described in paragraph (1) shall be in an amount equal to the charge imposed by the Secretary of Veterans Affairs for such services, or (if less) the amount that would be payable for such services under subsection (b) and section 1886 (as estimated by the Secretary). Any such payment shall be made to the entity to which payment for the services involved would have been payable, if payment for such services had been made by the individual receiving the services involved (or by another private person acting on behalf of such individual).

Payment for Hospice Care

(i)(1)(A) Subject to the limitation under paragraph (2) and the provisions of section 1813(a)(4) and except as otherwise provided in this paragraph, the amount paid to a hospice program with respect to hospice care for which payment may be made under this part shall be an amount equal to the costs which are reasonable and related to the cost of providing hospice care or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations (including those authorized under section 1861(v)(1)(A)), except that no payment may be made for bereavement counseling and no reimbursement may be made for other counseling services (including nutritional and dietary counseling) as separate services.

(B) Notwithstanding subparagraph (A), for hospice care furnished on or after April 1, 1986, the daily rate of payment per day for routine home care shall be $63.17 and the daily rate of payment for other services included in hospice care shall be the daily rate of payment recognized under subparagraph (A) as of July 1, 1985, increased by $10.

(C)(i) With respect to routine home care and other services included in hospice care furnished on or after January 1, 1990, and on or before September 30, 1990, the payment rates for such care and services shall be 120 percent of such rates in effect as of September 30, 1989.

(ii) With respect to routine home care and other services included in hospice care furnished during a subsequent fiscal year (before the first fiscal year in which the payment revisions described in paragraph (6)(D) are implemented), the payment rates for such care and services shall be the payment rates in effect under this subparagraph during the previous fiscal year increased by—

(I) for a fiscal year ending on or before September 30, 1993, the market basket percentage increase (as defined in section 1886(b)(3)(B)(iii)) for the fiscal year;

(II) for fiscal year 1994, the market basket percentage increase for the fiscal year minus 2.0 percentage points;

(III) for fiscal year 1995, the market basket percentage increase for the fiscal year minus 1.5 percentage points;

(IV) for fiscal year 1996, the market basket percentage increase for the fiscal year minus 1.5 percentage points;

(V) for fiscal year 1997, the market basket percentage increase for the fiscal year minus 0.5 percentage point;

(VI) for each of fiscal years 1998 through 2002, the market basket percentage increase for the fiscal year involved minus 1.0 percentage points, plus, in the case of fiscal year 2001, 5.0 percentage points; and

(VII) for a subsequent fiscal year (before the first fiscal year in which the payment revisions described in paragraph (6)(D) are implemented), subject to clauses (iv) and (vi), the market basket percentage increase for the fiscal year.

(iii) With respect to routine home care and other services included in hospice care furnished during fiscal years subsequent to the first fiscal year in which payment revisions described in paragraph (6)(D) are implemented, the payment rates for such care and services shall be the payment rates in effect under this clause during the preceding fiscal year increased by, subject to clauses (iv) and (vi), the market basket percentage increase (as defined in section 1886(b)(3)(B)(iii)) for the fiscal year.

(iv) Subject to clause (vi), after determining the market basket percentage increase under clause (ii)(VII) or (iii), as applicable, with respect to fiscal year 2013 and each subsequent fiscal year, the Secretary shall reduce such percentage—

(I) for 2013 and each subsequent fiscal year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(II) subject to clause (v), for each of fiscal years 2013 through 2019, by 0.3 percentage point.

The application of this clause may result in the market basket percentage increase under clause (ii)(VII) or (iii), as applicable, being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(v) Clause (iv)(II) shall be applied with respect to any of fiscal years 2014 through 2019 by substituting "0.0 percentage points" for "0.3 percentage point", if for such fiscal year—

(I) the excess (if any) of—

(aa) the total percentage of the non-elderly insured population for the preceding fiscal year (based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Patient Protection and Affordable Care Act that, if determined in the affirmative, would clear such Act for enrollment); over

(bb) the total percentage of the non-elderly insured population for such preceding fiscal year (as estimated by the Secretary); exceeds

(II) 5 percentage points.

(vi) For fiscal year 2018, the market basket percentage increase under clause (ii)(VII) or (iii), as applicable, after application of clause (iv), shall be 1 percent.

(2)(A) The amount of payment made under this part for hospice care provided by (or under arrangements made by) a hospice program for an accounting year may not exceed the "cap amount" for the year (computed under subparagraph (B)) multiplied by the number of medicare beneficiaries in the hospice program in that year (determined under subparagraph (C)).

(B) (i) Except as provided in clause (ii), for purposes of subparagraph (A), the "cap amount" for a year is $6,500, increased or decreased, for accounting years that end after October 1, 1984, by the same percentage as the percentage increase or decrease, respectively, in the medical care expenditure category of the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, from March 1984 to the fifth month of the accounting year.

(ii) For purposes of subparagraph (A) for accounting years that end after September 30, 2016, and before October 1, 2025, the "cap amount" is the cap amount under this subparagraph for the preceding accounting year updated by the percentage update to payment rates for hospice care under paragraph (1)(C) for services furnished during the fiscal year beginning on the October 1 preceding the beginning of the accounting year (including the application of any productivity or other adjustment under clause (iv) of that paragraph).

(iii) For accounting years that end after September 30, 2025, the cap amount shall be computed under clause (i) as if clause (ii) had never applied.

(C) For purposes of subparagraph (A), the "number of medicare beneficiaries" in a hospice program in an accounting year is equal to the number of individuals who have made an election under subsection (d) with respect to the hospice program and have been provided hospice care by (or under arrangements made by) the hospice program under this part in the accounting year, such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year or under a plan of care established by another hospice program.

(D) A hospice program shall submit claims for payment for hospice care furnished in an individual's home under this title only on the basis of the geographic location at which the service is furnished, as determined by the Secretary.

(3) Hospice programs providing hospice care for which payment is made under this subsection shall submit to the Secretary such data with respect to the costs for providing such care for each fiscal year, beginning with fiscal year 1999, as the Secretary determines necessary.

(4) The amount paid to a hospice program with respect to the services under section 1812(a)(5) for which payment may be made under this part shall be equal to an amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring medical decisionmaking of low complexity under the fee schedule established under section 1848(b), other than the portion of such amount attributable to the practice expense component.

(5) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of fiscal year 2014 and each subsequent fiscal year, in the case of a hospice program that does not submit data to the Secretary in accordance with subparagraph (C) with respect to such a fiscal year, after determining the market basket percentage increase under paragraph (1)(C)(ii)(VII) or paragraph (1)(C)(iii), as applicable, and after application of clauses (iv) and (vi) of paragraph (1)(C), with respect to the fiscal year, the Secretary shall reduce such market basket percentage increase by 2 percentage points *(or, for fiscal year 2023 and each subsequent fiscal year, 4 percentage points)*.

(ii) SPECIAL RULE.—The application of this subparagraph may result in the market basket percentage increase under paragraph (1)(C)(ii)(VII) or paragraph (1)(C)(iii), as applicable, being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the payment amount under this subsection for a subsequent fiscal year.

(C) SUBMISSION OF QUALITY DATA.—For fiscal year 2014 and each subsequent fiscal year, each hospice program shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that

is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to fiscal year 2014.

(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraph (C) available to the public. Such procedures shall ensure that a hospice program has the opportunity to review the data that is to be made public with respect to the hospice program prior to such data being made public. The Secretary shall report quality measures that relate to hospice care provided by hospice programs on the Internet website of the Centers for Medicare & Medicaid Services.

(6)(A) The Secretary shall collect additional data and information as the Secretary determines appropriate to revise payments for hospice care under this subsection pursuant to subparagraph (D) and for other purposes as determined appropriate by the Secretary. The Secretary shall begin to collect such data by not later than January 1, 2011.

(B) The additional data and information to be collected under subparagraph (A) may include data and information on—

(i) charges and payments;

(ii) the number of days of hospice care which are attributable to individuals who are entitled to, or enrolled for, benefits under part A; and

(iii) with respect to each type of service included in hospice care—

(I) the number of days of hospice care attributable to the type of service;

(II) the cost of the type of service; and

(III) the amount of payment for the type of service;

(iv) charitable contributions and other revenue of the hospice program;

(v) the number of hospice visits;

(vi) the type of practitioner providing the visit; and

(vii) the length of the visit and other basic information with respect to the visit.

(C) The Secretary may collect the additional data and information under subparagraph (A) on cost reports, claims, or other mechanisms as the Secretary determines to be appropriate.

(D)(i) Notwithstanding the preceding paragraphs of this subsection, not earlier than October 1, 2013, the Secretary shall, by regulation, implement revisions to the methodology for determining the payment rates for routine home care and other services included in hospice care under this part, as the Secretary determines to be appropriate. Such revisions may be based on an analysis of data and information collected under subparagraph (A). Such revisions may include adjustments to per diem payments that reflect changes in resource intensity

in providing such care and services during the course of the entire episode of hospice care.

(ii) Revisions in payment implemented pursuant to clause (i) shall result in the same estimated amount of aggregate expenditures under this title for hospice care furnished in the fiscal year in which such revisions in payment are implemented as would have been made under this title for such care in such fiscal year if such revisions had not been implemented.

(E) The Secretary shall consult with hospice programs and the Medicare Payment Advisory Commission regarding the additional data and information to be collected under subparagraph (A) and the payment revisions under subparagraph (D).

(7) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.

Elimination of Lesser-of-Cost-or-Charges Provision

(j)(1) The lesser-of-cost-or-charges provisions (described in paragraph (2)) will not apply in the case of services provided by a class of provider of services if the Secretary determines and certifies to Congress that the failure of such provisions to apply to the services provided by that class of providers will not result in any increase in the amount of payments made for those services under this title. Such change will take effect with respect to services furnished, or cost reporting periods of providers, on or after such date as the Secretary shall provide in the certification. Such change for a class of provider shall be discontinued if the Secretary determines and notifies Congress that such change has resulted in an increase in the amount of payments made under this title for services provided by that class of provider.

(2) The lesser-of-cost-or-charges provisions referred to in paragraph (1) are as follows:

(A) Clause (B) of paragraph (1) and paragraph (2) of subsection (b).

(B) Section 1834(a)(1)(B).

(C) So much of subparagraph (A) of section 1833(a)(2) as provides for payment other than of the reasonable cost of such services, as determined under section 1861(v).

(D) Subclause (II) of clause (i) and clause (ii) of section 1833(a)(2)(B).

Payments to Home Health Agencies for Durable Medical Equipment

(k) The amount paid to any home health agency with respect to durable medical equipment for which payment may be made under this part shall be the amount described in section 1834(a)(1).

Payment for Inpatient Critical Access Hospital Services

(l)(1) Except as provided in the subsequent paragraphs of this subsection, the amount of payment under this part for inpatient critical access hospital services is equal to 101 percent of the reasonable costs of the critical access hospital in providing such services.

(2) In the case of a distinct part psychiatric or rehabilitation unit of a critical access hospital described in section 1820(c)(2)(E), the amount of payment for inpatient critical access hospital services of such unit shall be equal to the amount of the payment that would otherwise be made if such services were inpatient hospital services of a distinct part psychiatric or rehabilitation unit, respectively, described in the matter following clause (v) of section 1886(d)(1)(B).

(3)(A) The following rules shall apply in determining payment and reasonable costs under paragraph (1) for costs described in subparagraph (C) for a critical access hospital that would be a meaningful EHR user (as would be determined under paragraph (3) of section 1886(n)) for an EHR reporting period for a cost reporting period beginning during a payment year if such critical access hospital was treated as an eligible hospital under such section:

(i) The Secretary shall compute reasonable costs by expensing such costs in a single payment year and not depreciating such costs over a period of years (and shall include as costs with respect to cost reporting periods beginning during a payment year costs from previous cost reporting periods to the extent they have not been fully depreciated as of the period involved).

(ii) There shall be substituted for the Medicare share that would otherwise be applied under paragraph (1) a percent (not to exceed 100 percent) equal to the sum of—

(I) the Medicare share (as would be specified under paragraph (2)(D) of section 1886(n)) for such critical access hospital if such critical access hospital was treated as an eligible hospital under such section; and

(II) 20 percentage points.

(B) The payment under this paragraph with respect to a critical access hospital shall be paid through a prompt interim payment (subject to reconciliation) after submission and review of such information (as specified by the Secretary) necessary to make such payment, including information necessary to apply this paragraph. In no case may payment under this paragraph be made with respect to a cost reporting period beginning during a payment year after 2015 and in no case may a critical access hospital receive payment under this paragraph with respect to more than 4 consecutive payment years.

(C) The costs described in this subparagraph are costs for the purchase of certified EHR technology to which purchase depreciation (excluding interest) would apply if payment was made under paragraph (1) and not under this paragraph.

(D) For purposes of this paragraph, paragraph (4), and paragraph (5), the terms "certified EHR technology", "eligible hospital", "EHR reporting period", and "payment year" have the meanings given such terms in sections 1886(n).

(4)(A) Subject to subparagraph (C), for cost reporting periods beginning in fiscal year 2015 or a subsequent fiscal year, in the case of a critical access hospital that is not a meaningful EHR user (as would be determined under paragraph (3) of section 1886(n) if such critical access hospital was treated as an eligible hospital under such section) for an EHR reporting period with respect to such fiscal year, paragraph (1) shall be applied by substituting the applica-

ble percent under subparagraph (B) for the percent described in such paragraph (1).

(B) The percent described in this subparagraph is—

(i) for fiscal year 2015, 100.66 percent;

(ii) for fiscal year 2016, 100.33 percent; and

(iii) for fiscal year 2017 and each subsequent fiscal year, 100 percent.

(C) The provisions of subclause (II) of section 1886(b)(3)(B)(ix) shall apply with respect to subparagraph (A) for a critical access hospital with respect to a cost reporting period beginning in a fiscal year in the same manner as such subclause applies with respect to subclause (I) of such section for a subsection (d) hospital with respect to such fiscal year.

(5) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

(A) the methodology and standards for determining the amount of payment and reasonable cost under paragraph (3) and payment adjustments under paragraph (4), including selection of periods under section 1886(n)(2) for determining, and making estimates or using proxies of, inpatient-bed-days, hospital charges, charity charges, and Medicare share under subparagraph (D) of section 1886(n)(2);

(B) the methodology and standards for determining a meaningful EHR user under section 1886(n)(3) as would apply if the hospital was treated as an eligible hospital under section 1886(n), and the hardship exception under paragraph (4)(C);

(C) the specification of EHR reporting periods under section 1886(n)(6)(B) as applied under paragraphs (3) and (4); and

(D) the identification of costs for purposes of paragraph (3)(C).

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SEC. 1822. HOSPICE PROGRAM SURVEY AND ENFORCEMENT PROCEDURES.

(a) SURVEYS.—

(1) FREQUENCY.—Any entity that is certified as a hospice program shall be subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months (and not less frequently than once every 24 months beginning October 1, 2021).

(2) PUBLIC TRANSPARENCY OF SURVEY AND CERTIFICATION INFORMATION.—

(A) SUBMISSION OF INFORMATION TO THE SECRETARY.—

(i) IN GENERAL.—Each State, and each national accreditation body with respect to which the Secretary has made a finding under section 1865(a) respecting the accreditation of a hospice program by such body, shall submit, in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph, information respecting any survey or certification made with respect to a hospice program by such State or body, as applicable. Such information shall include any inspection report made by such State or body with respect to such survey or certification, any

enforcement actions taken as a result of such survey or certification, and any other information determined appropriate by the Secretary.

(ii) REQUIRED INCLUSION OF SPECIFIED FORM.—With respect to a survey under this subsection carried out by a national accreditation body described in clause (i) on or after October 1, 2021, information described in such clause shall include Form 2567 (or a successor form), along with such additional information determined appropriate by such body.

(B) PUBLIC DISCLOSURE OF INFORMATION.—Beginning not later than October 1, 2022, the Secretary shall publish the information submitted under subparagraph (A) on the public website of the Centers for Medicare & Medicaid Services in a manner that is prominent, easily accessible, readily understandable, and searchable. The Secretary shall provide for the timely update of such information so published.

(3) CONSISTENCY OF SURVEYS.—Each State and the Secretary shall implement programs to measure and reduce inconsistency in the application of survey results among surveyors.

(4) SURVEY TEAMS.—

(A) IN GENERAL.—In the case of a survey conducted under this subsection on or after October 1, 2021, by more than 1 individual, such survey shall be conducted by a multidisciplinary team of professionals (including a registered professional nurse).

(B) PROHIBITION OF CONFLICTS OF INTEREST.—Beginning October 1, 2021, a State may not use as a member of a survey team under this subsection an individual who is serving (or has served within the previous 2 years) as a member of the staff of, or as a consultant to, the program surveyed respecting compliance with the requirements of section 1861(dd) or who has a personal or familial financial interest in the program being surveyed.

(C) TRAINING.—The Secretary shall provide, not later than October 1, 2021, for the comprehensive training of State and Federal surveyors, and any surveyor employed by a national accreditation body described in paragraph (2)(A)(i), in the conduct of surveys under this subsection, including training with respect to the review of written plans for providing hospice care (as described in section 1814(a)(7)(B)). No individual shall serve as a member of a survey team with respect to a survey conducted on or after such date unless the individual has successfully completed a training and testing program in survey and certification techniques that has been approved by the Secretary.

(5) FUNDING.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 to the Centers for Medicare & Medicaid Program Management Account, of $10,000,000 for each fiscal year (beginning with fiscal year 2022) for purposes of carrying out surveys under this subsection. Sums so transferred shall remain available until expended. Any transfer pursuant to this paragraph shall be in addition to any transfer pursuant to section 3(a)(2)

of the Improving Medicare Post-Acute Care Transformation Act of 2014.

(b) SPECIAL FOCUS PROGRAM.—

(1) IN GENERAL.—The Secretary shall conduct a special focus program for enforcement of requirements for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements of this Act.

(2) PERIODIC SURVEYS.—Under such special focus program, the Secretary shall conduct surveys of each hospice program in the special focus program not less than once every 6 months.

(c) ENFORCEMENT.—

(1) SITUATIONS INVOLVING IMMEDIATE JEOPARDY.—If the Secretary determines on the basis of a standard survey or otherwise that a hospice program that is certified for participation under this title is no longer in compliance with the requirements specified in section 1861(dd) and determines that the deficiencies involved immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy described in paragraph (5)(B)(iii) or terminate the certification of the program, and may provide, in addition, for 1 or more of the other remedies described in paragraph (5)(B).

(2) SITUATIONS NOT INVOLVING IMMEDIATE JEOPARDY.—If the Secretary determines on the basis of a standard survey or otherwise that a hospice program that is certified for participation under this title is no longer in compliance with the requirements specified in section 1861(dd) and determines that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary may (for a period not to exceed 6 months) impose remedies developed pursuant to paragraph (5)(A), in lieu of terminating the certification of the program. If, after such a period of remedies, the program is still no longer in compliance with such requirements, the Secretary shall terminate the certification of the program.

(3) PENALTY FOR PREVIOUS NONCOMPLIANCE.—If the Secretary determines that a hospice program that is certified for participation under this title is in compliance with the requirements specified in section 1861(dd) but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil monetary penalty under paragraph (5)(B)(i) for the days in which the Secretary finds that the program was not in compliance with such requirements.

(4) OPTION TO CONTINUE PAYMENTS FOR NONCOMPLIANT HOSPICE PROGRAMS.—The Secretary may continue payments under this title with respect to a hospice program not in compliance with the requirements specified in section 1861(dd) over a period of not longer than 6 months, if—

(A) the State or local survey agency finds that it is more appropriate to take alternative action to assure compliance of the program with such requirements than to terminate the certification of the program;

(B) the program has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action; and

(C) the program agrees to repay to the Federal Government payments received under this title during such period if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by hospice programs under this paragraph.

(5) REMEDIES.—

(A) DEVELOPMENT.—

(i) IN GENERAL.—Not later than October 1, 2021, the Secretary shall develop and implement—

(I) a range of remedies to apply to hospice programs under the conditions described in paragraphs (1) through (4); and

(II) appropriate procedures for appealing determinations relating to the imposition of such remedies.

Remedies developed pursuant to the preceding sentence shall include the remedies specified in subparagraph (B).

(ii) CONDITIONS OF IMPOSITION OF REMEDIES.—Not later than October 1, 2021, the Secretary shall develop and implement specific procedures with respect to the conditions under which each of the remedies developed under clause (i) is to be applied, including the amount of any fines and the severity of each of these remedies. Such procedures shall be designed so as to minimize the time between identification of deficiencies and imposition of these remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies.

(B) SPECIFIED REMEDIES.—The remedies specified in this subparagraph are the following:

(i) Civil monetary penalties in an amount not to exceed $10,000 for each day of noncompliance by a hospice program with the requirements specified in section 1861(dd).

(ii) Suspension of all or part of the payments to which a hospice program would otherwise be entitled under this title with respect to items and services furnished by a hospice program on or after the date on which the Secretary determines that remedies should be imposed pursuant to paragraph (2).

(iii) The appointment of temporary management to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made in order to bring the program into compliance with all such requirements.

(C) PROCEDURES.—

(i) CIVIL MONETARY PENALTIES.—

(I) IN GENERAL.—Subject to subclause (II), the provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(II) RETENTION OF AMOUNTS FOR HOSPICE PROGRAM IMPROVEMENTS.—The Secretary may provide that any portion of civil monetary penalties collected under this subsection may be used to support activities that benefit individuals receiving hospice care, including education and training programs to ensure hospice program compliance with the requirements of section 1861(dd).

(ii) SUSPENSION OF PAYMENT.—A finding to suspend payment under subparagraph (B)(ii) shall terminate when the Secretary finds that the program is in substantial compliance with all such requirements.

(iii) TEMPORARY MANAGEMENT.—The temporary management under subparagraph (B)(iii) shall not be terminated until the Secretary has determined that the program has the management capability to ensure continued compliance with all the requirements referred to in such subparagraph.

(D) RELATIONSHIP TO OTHER REMEDIES.—The remedies developed under subparagraph (A) are in addition to sanctions otherwise available under State or Federal law and shall not be construed as limiting other remedies, including any remedy available to an individual at common law.

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PART E—MISCELLANEOUS PROVISIONS

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

Spell of Illness

(a) The term "spell of illness" with respect to any individual means a period of consecutive days—

(1) beginning with the first day (not included in a previous spell of illness) (A) on which such individual is furnished inpatient hospital services, inpatient critical access hospital services or extended care services, and (B) which occurs in a month for which he is entitled to benefits under part A, and

(2) ending with the close of the first period of 60 consecutive days thereafter on each of which he is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1819(a)(1) or subsection (y)(1).

Inpatient Hospital Services

(b) The term "inpatient hospital services" means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital—

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;

excluding, however—

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

Paragraph (4) shall not apply to services provided in a hospital by—

(6) an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association or, in the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, or, in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association, or in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association; or

(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this title for reasonable costs of such services, and (B) all physicians in such hospital agree not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this title.

Inpatient Psychiatric Hospital Services

(c) The term "inpatient psychiatric hospital services" means inpatient hospital services furnished to an inpatient of a psychiatric hospital.

Supplier

(d) The term "supplier" means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

Hospital

(e) The term "hospital" (except for purposes of sections 1814(d), 1814(f), and 1835(b), subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which—

(1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient with respect to whom payment may be made under this title must be under the care of a physician, except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;

(5) provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times; except that until January 1, 1979, the Secretary is authorized to waive the requirement of this paragraph for any one-year period with respect to any institution, insofar as such requirement relates to the provision of twenty-four-hour nursing service rendered or supervised by a registered professional nurse (except that in any event a registered professional nurse must be present on the premises to render or supervise the nursing service provided, during at least the regular daytime shift), where immediately preceding such one-year period he finds that—

(A) such institution is located in a rural area and the supply of hospital services in such area is not sufficient to meet the needs of individuals residing therein,

(B) the failure of such institution to qualify as a hospital would seriously reduce the availability of such services to such individuals, and

(C) such institution has made and continues to make a good faith effort to comply with this paragraph, but such compliance is impeded by the lack of qualified nursing personnel in such area;

(6)(A) has in effect a hospital utilization review plan which meets the requirements of subsection (k) and (B) has in place a discharge planning process that meets the requirements of subsection (ee);

(7) in the case of an institution in any State in which State or applicable local law provides for the licensing of hospitals, (A) is licensed pursuant to such law or (B) is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing;

(8) has in effect an overall plan and budget that meets the requirements of subsection (z); and

(9) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

For purposes of subsection (a)(2), such term includes any institution which meets the requirements of paragraph (1) of this subsection. For purposes of sections 1814(d) and 1835(b) (including determination of whether an individual received inpatient hospital services or diagnostic services for purposes of such sections), section 1814(f)(2), and subsection (i) of this section, such term includes any institution which (i) meets the requirements of paragraphs (5) and (7) of this subsection, (ii) is not primarily engaged in providing the services described in section 1861(j)(1)(A) and (iii) is primarily engaged in providing, by or under the supervision of individuals referred to in paragraph (1) of section 1861(r), to inpatients diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. For purposes of section 1814(f)(1), such term includes an institution which (i) is a hospital for purposes of sections 1814(d), 1814(f)(2), and 1835(b) and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1865(a), or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of such a national accreditation body.. Notwithstanding the preceding provisions of this subsection, such term shall not, except for purposes of subsection (a)(2), include any institution which is primarily for the care and treatment of mental diseases unless it is a psychiatric hospital (as defined in subsection (f)). The term "hospital" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 1865. The term "hospital" also includes a facility of fifty beds or less which is located in an area determined by the Secretary to meet the definition relating to a rural area described in subparagraph (A) of paragraph (5) of this subsection and which meets the other requirements of this subsection, except that—

(A) with respect to the requirements for nursing services applicable after December 31, 1978, such requirements shall provide for temporary waiver of the requirements, for such period as the Secretary deems appropriate, where (i) the facility's failure to fully comply with the requirements is attributable to a temporary shortage of qualified nursing personnel in the area in which the facility is located, (ii) a registered professional nurse is present on the premises to render or supervise the nursing service provided during at least the regular daytime shift, and (iii) the Secretary determines that the employment

of such nursing personnel as are available to the facility during such temporary period will not adversely affect the health and safety of patients;

(B) with respect to the health and safety requirements promulgated under paragraph (9), such requirements shall be applied by the Secretary to a facility herein defined in such manner as to assure that personnel requirements take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which such facility is located, and the scope of services rendered by such facility; and the Secretary, by regulations, shall provide for the continued participation of such a facility where such personnel requirements are not fully met, for such period as the Secretary determines that (i) the facility is making good faith efforts to fully comply with the personnel requirements, (ii) the employment by the facility of such personnel as are available to the facility will not adversely affect the health and safety of patients, and (iii) if the Secretary has determined that because of the facility's waiver under this subparagraph the facility should limit its scope of services in order not to adversely affect the health and safety of the facility's patients, the facility is so limiting the scope of services it provides; and

(C) with respect to the fire and safety requirements promulgated under paragraph (9), the Secretary (i) may waive, for such period as he deems appropriate, specific provisions of such requirements which if rigidly applied would result in unreasonable hardship for such a facility and which, if not applied, would not jeopardize the health and safety of patients, and (ii) may accept a facility's compliance with all applicable State codes relating to fire and safety in lieu of compliance with the fire and safety requirements promulgated under paragraph (9), if he determines that such State has in effect fire and safety codes, imposed by State law, which adequately protect patients.

The term "hospital" does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1)).

Psychiatric Hospital

(f) The term "psychiatric hospital" means an institution which—

(1) is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

(2) satisfies the requirements of paragraphs (3) through (9) of subsection (e);

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under part A; and

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals who are furnished services in the institution.

In the case of an institution which satisfies paragraphs (1) and (2) of the preceding sentence and which contains a distinct part which also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a "psychiatric hospital".

Outpatient Occupational Therapy Services

(g) The term "outpatient occupational therapy services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that "occupational" shall be substituted for "physical" each place it appears therein.

Extended Care Services

(h) The term "extended care services" means the following items and services furnished to an inpatient of a skilled nursing facility and (except as provided in paragraphs (3), (6) and (7)) by such skilled nursing facility—

(1) nursing care provided by or under the supervision of a registered professional nurse;

(2) bed and board in connection with the furnishing of such nursing care;

(3) physical or occupational therapy or speech-language pathology services furnished by the skilled nursing facility or by others under arrangements with them made by the facility;

(4) medical social services;

(5) such drugs, biologicals, supplies, appliances, and equipment, furnished for use in the skilled nursing facility, as are ordinarily furnished by such facility for the care and treatment of inpatients;

(6) medical services provided by an intern or resident-in-training of a hospital with which the facility has in effect a transfer agreement (meeting the requirements of subsection (l)), under a teaching program of such hospital approved as provided in the last sentence of subsection (b), and other diagnostic or therapeutic services provided by a hospital with which the facility has such an agreement in effect; and

(7) such other services necessary to the health of the patients as are generally provided by skilled nursing facilities, or by others under arrangements with them made by the facility;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital.

Post-Hospital Extended Care Services

(i) The term "post-hospital extended care services" means extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer. For purposes of the preceding sentence, items and services shall be deemed to have been furnished to an individual after transfer from a hospital, and he shall be deemed to have been an inpatient in the hospital immediately before transfer therefrom, if he is admitted to the skilled nursing facility (A) within 30 days after discharge from such hospital, or (B) within such time as it would be medically appropriate to begin an active course of treatment, in the case of an individual whose condition is such that

skilled nursing facility care would not be medically appropriate within 30 days after discharge from a hospital; and an individual shall be deemed not to have been discharged from a skilled nursing facility if, within 30 days after discharge therefrom, he is admitted to such facility or any other skilled nursing facility.

Skilled Nursing Facility

(j) The term "skilled nursing facility" has the meaning given such term in section 1819(a).

Utilization Review

(k) A utilization review plan of a hospital or skilled nursing facility shall be considered sufficient if it is applicable to services furnished by the institution to individuals entitled to insurance benefits under this title and if it provides—

(1) for the review, on a sample or other basis, of admissions to the institution, the duration of stays therein, and the professional services (including drugs and biologicals) furnished, (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services;

(2) for such review to be made by either (A) a staff committee of the institution composed of two or more physicians (of which at least two must be physicians described in subsection (r)(1) of this section), with or without participation of other professional personnel, or (B) a group outside the institution which is similarly composed and (i) which is established by the local medical society and some or all of the hospitals and skilled nursing facilities in the locality, or (ii) if (and for as long as) there has not been established such a group which serves such institution, which is established in such other manner as may be approved by the Secretary;

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continuous period of extended duration, as of such days of such period (which may differ for different classes of cases) as may be specified in regulations, with such review to be made as promptly as possible, after each day so specified, and in no event later than one week following such day; and

(4) for prompt notification to the institution, the individual, and his attending physician of any finding (made after opportunity for consultation to such attending physician) by the physician members of such committee or group that any further stay in the institution is not medically necessary.

The review committee must be composed as provided in clause (B) of paragraph (2) rather than as provided in clause (A) of such paragraph in the case of any hospital or skilled nursing facility where, because of the small size of the institution, or (in the case of a skilled nursing facility) because of lack of an organized medical staff, or for such other reason or reasons as may be included in regulations, it is impracticable for the institution to have a properly functioning staff committee for the purposes of this subsection. If the Secretary determines that the utilization review procedures established pursuant to title XIX are superior in their effectiveness

to the procedures required under this section, he may, to the extent that he deems it appropriate, require for purposes of this title that the procedures established pursuant to title XIX be utilized instead of the procedures required by this section.

Agreements for Transfer Between Skilled Nursing Facilities and Hospitals

(l) A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case the two institutions are under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that—

(1) transfer of patients will be effected between the hospital and the skilled nursing facility whenever such transfer is medically appropriate as determined by the attending physician; and

(2) there will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.

Any skilled nursing facility which does not have such an agreement in effect, but which is found by a State agency (of the State in which such facility is situated) with which an agreement under section 1864 is in effect (or, in the case of a State in which no such agency has an agreement under section 1864, by the Secretary) to have attempted in good faith to enter into such an agreement with a hospital sufficiently close to the facility to make feasible the transfer between them of patients and the information referred to in paragraph (2), shall be considered to have such an agreement in effect if and for so long as such agency (or the Secretary, as the case may be) finds that to do so is in the public interest and essential to assuring extended care services for persons in the community who are eligible for payments with respect to such services under this title.

Home Health Services

(m) The term "home health services" means the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are, except as provided in paragraph (7), provided on a visiting basis in a place of residence used as such individual's home—

(1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(2) physical or occupational therapy or speech-language pathology services;

(3) medical social services under the direction of a physician;

(4) to the extent permitted in regulations, part-time or intermittent services of a home health aide who has successfully completed a training program approved by the Secretary;

(5) medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk)), but excluding other drugs and biologicals) and durable medical equipment and applicable disposable devices (as defined in section 1834(s)(2)) while under such a plan;

(6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b); and

(7) any of the foregoing items and services which are provided on an outpatient basis, under arrangements made by the home health agency, at a hospital or skilled nursing facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations, and—

(A) the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in such place of residence, or

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A),

but not including transportation of the individual in connection with any such item or service;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital and home infusion therapy (as defined in subsection (iii)(i)). For purposes of paragraphs (1) and (4), the term "part-time or intermittent services" means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1814(a)(2)(C) and 1835(a)(2)(A), "intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

Durable Medical Equipment

(n) The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in con-

sultation with the appropriate organizations) and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories; except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

Home Health Agency

(o) The term "home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which—

(1) is primarily engaged in providing skilled nursing services and other therapeutic services;

(2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;

(5) has in effect an overall plan and budget that meets the requirements of subsection (z);

(6) meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;

(7) provides the Secretary with a surety bond—

(A) in a form specified by the Secretary and in an amount that is not less than the minimum of $50,000; and

(B) that the Secretary determines is commensurate with the volume of payments to the home health agency; and

(8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program;

except that for purposes of part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.

Outpatient Physical Therapy Services

(p) The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient—

(1) who is under the care of a physician (as defined in paragraph (1), (3), or (4) of section 1861(r)), and

(2) with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished such individual has been established by a physician (as so defined) or by a qualified physical therapist and is periodically reviewed by a physician (as so defined);

excluding, however—

(3) any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital; and

(4) any such service—

(A) if furnished by a clinic or rehabilitation agency, or by others under arrangements with such clinic or agency, unless such clinic or rehabilitation agency—

(i) provides an adequate program of physical therapy services for outpatients and has the facilities and personnel required for such program or required for the supervision of such a program, in accordance with such requirements as the Secretary may specify,

(ii) has policies, established by a group of professional personnel, including one or more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) maintains clinical records on all patients,

(iv) if such clinic or agency is situated in a State in which State or applicable local law provides for the licensing of institutions of this nature, (I) is licensed pursuant to such law, or (II) is approved by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

(v) meets such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary, and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000, or

(B) if furnished by a public health agency, unless such agency meets such other conditions relating to health and safety of individuals who are furnished services by such agency on an outpatient basis, as the Secretary may find necessary.

The term "outpatient physical therapy services" also includes physical therapy services furnished an individual by a physical therapist (in his office or in such individual's home) who meets licensing

and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. In addition, such term includes physical therapy services which meet the requirements of the first sentence of this subsection except that they are furnished to an individual as an inpatient of a hospital or extended care facility. Nothing in this subsection shall be construed as requiring, with respect to outpatients who are not entitled to benefits under this title, a physical therapist to provide outpatient physical therapy services only to outpatients who are under the care of a physician or pursuant to a plan of care established by a physician. The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.

Physicians' Services

(q) The term "physicians' services" means professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6)).

Physician

(r) The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) and with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to prac-

tice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished.

Medical and Other Health Services

(s) The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1847B);

(B) hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are—

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services;

(E) rural health clinic services and Federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B)), including such renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services paid under section 1881(b)(14) to an individual with acute kidney injury (as defined in section 1834(r)(2));

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in section 1861(r)(1), for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1876 to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5)) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1876(g) to a member of an eligible organization

by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2)), and such services and supplies furnished as an incident to such clinical psychologist's services or clinical social worker's services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this title;

(K)(i) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a physician assistant (as defined in subsection (aa)(5)) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services,

(ii) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5)) working in collaboration (as defined in subsection (aa)(6)) with a physician (as defined in subsection (r)(1)) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

(L) certified nurse-midwife services;

(M) qualified psychologist services;

(N) clinical social worker services (as defined in subsection (hh)(2));

(O) erythropoietin for dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;

(P) prostate cancer screening tests (as defined in subsection (oo));

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer

chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;

(R) colorectal cancer screening tests (as defined in subsection (pp));

(S) diabetes outpatient self-management training services (as defined in subsection (qq));

(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)—

(i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and

(ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously;

(U) screening for glaucoma (as defined in subsection (uu)) for individuals determined to be at high risk for glaucoma, individuals with a family history of glaucoma and individuals with diabetes;

(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who—

(i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary;

(ii) is not receiving maintenance dialysis for which payment is made under section 1881; and

(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;

(W) an initial preventive physical examination (as defined in subsection (ww));

(X) cardiovascular screening blood tests (as defined in subsection (xx)(1));

(Y) diabetes screening tests (as defined in subsection (yy));

(Z) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (zz));

(AA) ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bbb)) for an individual—

(i) who receives a referral for such an ultrasound screening as a result of an initial preventive physical examination (as defined in section 1861(ww)(1));

(ii) who has not been previously furnished such an ultrasound screening under this title; and

(iii) who—

(I) has a family history of abdominal aortic aneurysm; or

(II) manifests risk factors included in a beneficiary category recommended for screening by the United

States Preventive Services Task Force regarding abdominal aortic aneurysms;

(BB) additional preventive services (described in subsection (ddd)(1));

(CC) items and services furnished under a cardiac rehabilitation program (as defined in subsection (eee)(1)) or under a pulmonary rehabilitation program (as defined in subsection (fff)(1));

(DD) items and services furnished under an intensive cardiac rehabilitation program (as defined in subsection (eee)(4));

(EE) kidney disease education services (as defined in subsection (ggg));

(FF) personalized prevention plan services (as defined in subsection (hhh));

(GG) home infusion therapy (as defined in subsection (iii)(1)); and

(HH) opioid use disorder treatment services (as defined in subsection (jjj)).

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but, subject to section 1834(l)(14), only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

(10)(A) pneumococcal vaccine and its administration and, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, influenza vaccine and its administration; and

(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);

(11) services of a certified registered nurse anesthetist (as defined in subsection (bb));

(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if—

(A) the physician who is managing the individual's diabetic condition (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);

(13) screening mammography (as defined in subsection (jj));

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement (as defined in subsection (rr)).

No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1814(d)) shall be included within paragraph (3) unless such laboratory—

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17)(A) meets the certification requirements under section 353 of the Public Health Service Act; and

(B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1814(d) shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

Drugs and Biologicals

(t)(1) The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) and paragraph (2), include only such

drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

(2)(A) For purposes of paragraph (1), the term "drugs" also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph (B)).

(B) In subparagraph (A), the term "medically accepted indication", with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—

(i) the drug has been approved by the Food and Drug Administration; and

(ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

(II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

The Secretary may revise the list of compendia in clause (ii)(I) as is appropriate for identifying medically accepted indications for drugs. On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

Provider of Services

(u) The term "provider of services" means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) and section 1835(e), a fund.

Reasonable Cost

(v)(1)(A) The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to

be included, in determining such costs for various types or classes of institutions, agencies, and services; except that in any case to which paragraph (2) or (3) applies, the amount of the payment determined under such paragraph with respect to the services involved shall be considered the reasonable cost of such services. In prescribing the regulations referred to in the preceding sentence, the Secretary shall consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in computing the amount of payment, to be made by persons other than the recipients of services, to providers of services on account of services furnished to such recipients by such providers. Such regulations may provide for determination of the costs of services on a per diem, per unit, per capita, or other basis, may provide for using different methods in different circumstances, may provide for the use of estimates of costs of particular items or services, may provide for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services or groups of items or services to be recognized as reasonable based on estimates of the costs necessary in the efficient delivery of needed health services to individuals covered by the insurance programs established under this title, and may provide for the use of charges or a percentage of charges where this method reasonably reflects the costs. Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this title) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this title will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive.

(B) In the case of extended care services, the regulations under subparagraph (A) shall not include provision for specific recognition of a return on equity capital.

(C) Where a hospital has an arrangement with a medical school under which the faculty of such school provides services at such hospital, an amount not in excess of the reasonable cost of such services to the medical school shall be included in determining the reasonable cost to the hospital of furnishing services—

(i) for which payment may be made under part A, but only if—

(I) payment for such services as furnished under such arrangement would be made under part A to the hospital had such services been furnished by the hospital, and

(II) such hospital pays to the medical school at least the reasonable cost of such services to the medical school, or

(ii) for which payment may be made under part B, but only if such hospital pays to the medical school at least the reasonable cost of such services to the medical school.

(D) Where (i) physicians furnish services which are either inpatient hospital services (including services in conjunction with the teaching programs of such hospital) by reason of paragraph (7) of subsection (b) or for which entitlement exists by reason of clause (II) of section 1832(a)(2)(B)(i), and (ii) such hospital (or medical school under arrangement with such hospital) incurs no actual cost in the furnishing of such services, the reasonable cost of such services shall (under regulations of the Secretary) be deemed to be the cost such hospital or medical school would have incurred had it paid a salary to such physicians rendering such services approximately equivalent to the average salary paid to all physicians employed by such hospital (or if such employment does not exist, or is minimal in such hospital, by similar hospitals in a geographic area of sufficient size to assure reasonable inclusion of sufficient physicians in development of such average salary).

(E) Such regulations may, in the case of skilled nursing facilities in any State, provide for the use of rates, developed by the State in which such facilities are located, for the payment of the cost of skilled nursing facility services furnished under the State's plan approved under title XIX (and such rates may be increased by the Secretary on a class or size of institution or on a geographical basis by a percentage factor not in excess of 10 percent to take into account determinable items or services or other requirements under this title not otherwise included in the computation of such State rates), if the Secretary finds that such rates are reasonably related to (but not necessarily limited to) analyses undertaken by such State of costs of care in comparable facilities in such State. Notwithstanding the previous sentence, such regulations with respect to skilled nursing facilities shall take into account (in a manner consistent with subparagraph (A) and based on patient-days of services furnished) the costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident eligible for benefits under this title) of such facilities complying with the requirements of subsections (b), (c), and (d) of section 1819 (including the costs of conducting nurse aide training and competency evaluation programs and competency evaluation programs).

(F) Such regulations shall require each provider of services (other than a fund) to make reports to the Secretary of information described in section 1121(a) in accordance with the uniform reporting system (established under such section) for that type of provider.

(G)(i) In any case in which a hospital provides inpatient services to an individual that would constitute post-hospital extended care services if provided by a skilled nursing facility and a quality improvement organization (or, in the absence of such a qualified organization, the Secretary or such agent as the Secretary may designate) determines that inpatient hospital services for the individual are not medically necessary but post-hospital extended care services for the individual are medically necessary and such extended care services are not otherwise available to the individual (as determined in accordance with criteria established by the Secretary) at the time of such determination, payment for such serv-

ices provided to the individual shall continue to be made under this title at the payment rate described in clause (ii) during the period in which—

(I) such post-hospital extended care services for the individual are medically necessary and not otherwise available to the individual (as so determined),

(II) inpatient hospital services for the individual are not medically necessary, and

(III) the individual is entitled to have payment made for post-hospital extended care services under this title,

except that if the Secretary determines that there is not an excess of hospital beds in such hospital and (subject to clause (iv)) there is not an excess of hospital beds in the area of such hospital, such payment shall be made (during such period) on the basis of the amount otherwise payable under part A with respect to inpatient hospital services.

(ii)(I) Except as provided in subclause (II), the payment rate referred to in clause (i) is a rate equal to the estimated adjusted State-wide average rate per patient-day paid for services provided in skilled nursing facilities under the State plan approved under title XIX for the State in which such hospital is located, or, if the State in which the hospital is located does not have a State plan approved under title XIX, the estimated adjusted State-wide average allowable costs per patient-day for extended care services under this title in that State.

(II) If a hospital has a unit which is a skilled nursing facility, the payment rate referred to in clause (i) for the hospital is a rate equal to the lesser of the rate described in subclause (I) or the allowable costs in effect under this title for extended care services provided to patients of such unit.

(iii) Any day on which an individual receives inpatient services for which payment is made under this subparagraph shall, for purposes of this Act (other than this subparagraph), be deemed to be a day on which the individual received inpatient hospital services.

(iv) In determining under clause (i), in the case of a public hospital, whether or not there is an excess of hospital beds in the area of such hospital, such determination shall be made on the basis of only the public hospitals (including the hospital) which are in the area of the hospital and which are under common ownership with that hospital.

(H) In determining such reasonable cost with respect to home health agencies, the Secretary may not include—

(i) any costs incurred in connection with bonding or establishing an escrow account by any such agency as a result of the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8);

(ii) in the case of home health agencies to which the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8) apply, any costs attributed to interest charged such an agency in connection with amounts borrowed by the agency to repay overpayments made under this title to the agency, except that such costs may be included in reasonable cost if the Secretary determines that the agency was acting in good faith in borrowing the amounts;

(iii) in the case of contracts entered into by a home health agency after the date of the enactment of this subparagraph for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract which is entered into for a period exceeding five years; and

(iv) in the case of contracts entered into by a home health agency before the date of the enactment of this subparagraph for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract, which determines the amount payable by the home health agency on the basis of a percentage of the agency's reimbursement or claim for reimbursement for services furnished by the agency, to the extent that such cost exceeds the reasonable value of the services furnished on behalf of such agency.

(I) In determining such reasonable cost, the Secretary may not include any costs incurred by a provider with respect to any services furnished in connection with matters for which payment may be made under this title and furnished pursuant to a contract between the provider and any of its subcontractors which is entered into after the date of the enactment of this subparagraph and the value or cost of which is $10,000 or more over a twelve-month period unless the contract contains a clause to the effect that—

(i) until the expiration of four years after the furnishing of such services pursuant to such contract, the subcontractor shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the contract, and books, documents and records of such subcontractor that are necessary to certify the nature and extent of such costs, and

(ii) if the subcontractor carries out any of the duties of the contract through a subcontract, with a value or cost of $10,000 or more over a twelve-month period, with a related organization, such subcontract shall contain a clause to the effect that until the expiration of four years after the furnishing of such services pursuant to such subcontract, the related organization shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the subcontract, and books, documents and records of such organization that are necessary to verify the nature and extent of such costs.

The Secretary shall prescribe in regulation criteria and procedures which the Secretary shall use in obtaining access to books, documents, and records under clauses required in contracts and subcontracts under this subparagraph.

(J) Such regulations may not provide for any inpatient routine salary cost differential as a reimbursable cost for hospitals and skilled nursing facilities.

(K)(i) The Secretary shall issue regulations that provide, to the extent feasible, for the establishment of limitations on the amount of any costs or charges that shall be considered reasonable with respect to services provided on an outpatient basis by hospitals (other than bona fide emergency services as defined in clause (ii)) or clinics (other than rural health clinics), which are reimbursed on a cost

basis or on the basis of cost related charges, and by physicians utilizing such outpatient facilities. Such limitations shall be reasonably related to the charges in the same area for similar services provided in physicians' offices. Such regulations shall provide for exceptions to such limitations in cases where similar services are not generally available in physicians' offices in the area to individuals entitled to benefits under this title.

(ii) For purposes of clause (i), the term "bona fide emergency services" means services provided in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(I) placing the patient's health in serious jeopardy;

(II) serious impairment to bodily functions; or

(III) serious dysfunction of any bodily organ or part.

(L)(i) The Secretary, in determining the amount of the payments that may be made under this title with respect to services furnished by home health agencies, may not recognize as reasonable (in the efficient delivery of such services) costs for the provision of such services by an agency to the extent these costs exceed (on the aggregate for the agency) for cost reporting periods beginning on or after—

(I) July 1, 1985, and before July 1, 1986, 120 percent of the mean of the labor-related and nonlabor per visit costs for freestanding home health agencies,

(II) July 1, 1986, and before July 1, 1987, 115 percent of such mean,

(III) July 1, 1987, and before October 1, 1997, 112 percent of such mean,

(IV) October 1, 1997, and before October 1, 1998, 105 percent of the median of the labor-related and nonlabor per visit costs for freestanding home health agencies, or

(V) October 1, 1998, 106 percent of such median.

(ii) Effective for cost reporting periods beginning on or after July 1, 1986, such limitations shall be applied on an aggregate basis for the agency, rather than on a discipline specific basis. The Secretary may provide for such exemptions and exceptions to such limitation as he deems appropriate.

(iii) Not later than July 1, 1991, and annually thereafter (but not for cost reporting periods beginning on or after July 1, 1994, and before July 1, 1996, or on or after July 1, 1997, and before October 1, 1997), the Secretary shall establish limits under this subparagraph for cost reporting periods beginning on or after such date by utilizing the area wage index applicable under section 1886(d)(3)(E) and determined using the survey of the most recent available wages and wage-related costs of hospitals located in the geographic area in which the home health service is furnished (determined without regard to whether such hospitals have been reclassified to a new geographic area pursuant to section 1886(d)(8)(B), a decision of the Medicare Geographic Classification Review Board under section 1886(d)(10), or a decision of the Secretary).

(iv) In establishing limits under this subparagraph for cost reporting periods beginning after September 30, 1997, the Secretary shall not take into account any changes in the home health market

basket, as determined by the Secretary, with respect to cost reporting periods which began on or after July 1, 1994, and before July 1, 1996.

(v) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, subject to clause (viii)(I), the Secretary shall provide for an interim system of limits. Payment shall not exceed the costs determined under the preceding provisions of this subparagraph or, if lower, the product of—

(I) an agency-specific per beneficiary annual limitation calculated based 75 percent on 98 percent of the reasonable costs (including nonroutine medical supplies) for the agency's 12-month cost reporting period ending during fiscal year 1994, and based 25 percent on 98 percent of the standardized regional average of such costs for the agency's census division, as applied to such agency, for cost reporting periods ending during fiscal year 1994, such costs updated by the home health market basket index; and

(II) the agency's unduplicated census count of patients (entitled to benefits under this title) for the cost reporting period subject to the limitation.

(vi) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, the following rules apply:

(I) For new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994 subject to clauses (viii)(II) and (viii)(III), the per beneficiary limitation shall be equal to the median of these limits (or the Secretary's best estimates thereof) applied to other home health agencies as determined by the Secretary. A home health agency that has altered its corporate structure or name shall not be considered a new provider for this purpose.

(II) For beneficiaries who use services furnished by more than one home health agency, the per beneficiary limitations shall be prorated among the agencies.

(vii)(I) Not later than January 1, 1998, the Secretary shall establish per visit limits applicable for fiscal year 1998, and not later than April 1, 1998, the Secretary shall establish per beneficiary limits under clause (v)(I) for fiscal year 1998.

(II) Not later than August 1 of each year (beginning in 1998) the Secretary shall establish the limits applicable under this subparagraph for services furnished during the fiscal year beginning October 1 of the year.

(viii)(I) In the case of a provider with a 12-month cost reporting period ending in fiscal year 1994, if the limit imposed under clause (v) (determined without regard to this subclause) for a cost reporting period beginning during or after fiscal year 1999 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by ⅓ of such difference.

(II) Subject to subclause (IV), for new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994, but for which the first cost reporting period begins before fiscal year 1999, for cost reporting periods beginning during or

after fiscal year 1999, the per beneficiary limitation described in clause (vi)(I) shall be equal to the median described in such clause (determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent").

(III) Subject to subclause (IV), in the case of a new provider for which the first cost reporting period begins during or after fiscal year 1999, the limitation applied under clause (vi)(I) (but only with respect to such provider) shall be equal to 75 percent of the median described in clause (vi)(I).

(IV) In the case of a new provider or a provider without a 12-month cost reporting period ending in fiscal year 1994, subclause (II) shall apply, instead of subclause (III), to a home health agency which filed an application for home health agency provider status under this title before September 15, 1998, or which was approved as a branch of its parent agency before such date and becomes a subunit of the parent agency or a separate agency on or after such date.

(V) Each of the amounts specified in subclauses (I) through (III) are such amounts as adjusted under clause (iii) to reflect variations in wages among different areas.

(ix) Notwithstanding the per beneficiary limit under clause (viii), if the limit imposed under clause (v) (determined without regard to this clause) for a cost reporting period beginning during or after fiscal year 2000 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by 2 percent.

(x) Notwithstanding any other provision of this subparagraph, in updating any limit under this subparagraph by a home health market basket index for cost reporting periods beginning during each of fiscal years 2000, 2002, and 2003, the update otherwise provided shall be reduced by 1.1 percentage points. With respect to cost reporting periods beginning during fiscal year 2001, the update to any limit under this subparagraph shall be the home health market basket index.

(M) Such regulations shall provide that costs respecting care provided by a provider of services, pursuant to an assurance under title VI or XVI of the Public Health Service Act that the provider will make available a reasonable volume of services to persons unable to pay therefor, shall not be allowable as reasonable costs.

(N) In determining such reasonable costs, costs incurred for activities directly related to influencing employees respecting unionization may not be included.

(O)(i) In establishing an appropriate allowance for depreciation and for interest on capital indebtedness with respect to an asset of a provider of services which has undergone a change of ownership, such regulations shall provide, except as provided in clause (iii), that the valuation of the asset after such change of ownership shall be the historical cost of the asset, as recognized under this title, less depreciation allowed, to the owner of record as of the date of enactment of the Balanced Budget Act of 1997 (or, in the case of an asset not in existence as of that date, the first owner of record of the asset after that date).

(ii) Such regulations shall not recognize, as reasonable in the provision of health care services, costs (including legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies) attributable to the negotiation or settlement of the sale or purchase of any capital asset (by acquisition or merger) for which any payment has previously been made under this title.

(iii) In the case of the transfer of a hospital from ownership by a State to ownership by a nonprofit corporation without monetary consideration, the basis for capital allowances to the new owner shall be the book value of the hospital to the State at the time of the transfer.

(P) If such regulations provide for the payment for a return on equity capital (other than with respect to costs of inpatient hospital services), the rate of return to be recognized, for determining the reasonable cost of services furnished in a cost reporting period, shall be equal to the average of the rates of interest, for each of the months any part of which is included in the period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(Q) Except as otherwise explicitly authorized, the Secretary is not authorized to limit the rate of increase on allowable costs of approved medical educational activities.

(R) In determining such reasonable cost, costs incurred by a provider of services representing a beneficiary in an unsuccessful appeal of a determination described in section 1869(b) shall not be allowable as reasonable costs.

(S)(i) Such regulations shall not include provision for specific recognition of any return on equity capital with respect to hospital outpatient departments.

(ii)(I) Such regulations shall provide that, in determining the amount of the payments that may be made under this title with respect to all the capital-related costs of outpatient hospital services, the Secretary shall reduce the amounts of such payments otherwise established under this title by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1990, by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1991, and by 10 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1992 through 1999 and until the first date that the prospective payment system under section 1833(t) is implemented.

(II) The Secretary shall reduce the reasonable cost of outpatient hospital services (other than the capital-related costs of such services) otherwise determined pursuant to section 1833(a)(2)(B)(i)(I) by 5.8 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1991 through 1999 and until the first date that the prospective payment system under section 1833(t) is implemented.

(III) Subclauses (I) and (II) shall not apply to payments with respect to the costs of hospital outpatient services provided by any hospital that is a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) or a critical access hospital (as defined in section 1861(mm)(1)).

(IV) In applying subclauses (I) and (II) to services for which payment is made on the basis of a blend amount under section

1833(i)(3)(A)(ii) or 1833(n)(1)(A)(ii), the costs reflected in the amounts described in sections 1833(i)(3)(B)(i)(I) and 1833(n)(1)(B)(i)(I), respectively, shall be reduced in accordance with such subclause.

(T) In determining such reasonable costs for hospitals, no reduction in copayments under section 1833(t)(8)(B) shall be treated as a bad debt and the amount of bad debts otherwise treated as allowable costs which are attributable to the deductibles and coinsurance amounts under this title shall be reduced—

(i) for cost reporting periods beginning during fiscal year 1998, by 25 percent of such amount otherwise allowable,

(ii) for cost reporting periods beginning during fiscal year 1999, by 40 percent of such amount otherwise allowable,

(iii) for cost reporting periods beginning during fiscal year 2000, by 45 percent of such amount otherwise allowable,

(iv) for cost reporting periods beginning during fiscal years 2001 through 2012, by 30 percent of such amount otherwise allowable, and

(v) for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(U) In determining the reasonable cost of ambulance services (as described in subsection (s)(7)) provided during fiscal year 1998, during fiscal year 1999, and during so much of fiscal year 2000 as precedes January 1, 2000, the Secretary shall not recognize the costs per trip in excess of costs recognized as reasonable for ambulance services provided on a per trip basis during the previous fiscal year (after application of this subparagraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the fiscal year involved reduced by 1.0 percentage point. For ambulance services provided after June 30, 1998, the Secretary may provide that claims for such services must include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(V) In determining such reasonable costs for skilled nursing facilities and (beginning with respect to cost reporting periods beginning during fiscal year 2013) for covered skilled nursing services described in section 1888(e)(2)(A) furnished by hospital providers of extended care services (as described in section 1883), the amount of bad debts otherwise treated as allowed costs which are attributable to the coinsurance amounts under this title for individuals who are entitled to benefits under part A and—

(i) are not described in section 1935(c)(6)(A)(ii) shall be reduced by—

(I) for cost reporting periods beginning on or after October 1, 2005, but before fiscal year 2013, 30 percent of such amount otherwise allowable; and

(II) for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(ii) are described in such section—

(I) for cost reporting periods beginning on or after October 1, 2005, but before fiscal year 2013, shall not be reduced;

(II) for cost reporting periods beginning during fiscal year 2013, shall be reduced by 12 percent of such amount otherwise allowable;

(III) for cost reporting periods beginning during fiscal year 2014, shall be reduced by 24 percent of such amount otherwise allowable; and

(IV) for cost reporting periods beginning during a subsequent fiscal year, shall be reduced by 35 percent of such amount otherwise allowable.

(W)(i) In determining such reasonable costs for providers described in clause (ii), the amount of bad debts otherwise treated as allowable costs which are attributable to deductibles and coinsurance amounts under this title shall be reduced—

(I) for cost reporting periods beginning during fiscal year 2013, by 12 percent of such amount otherwise allowable;

(II) for cost reporting periods beginning during fiscal year 2014, by 24 percent of such amount otherwise allowable; and

(III) for cost reporting periods beginning during a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(ii) A provider described in this clause is a provider of services not described in subparagraph (T) or (V), a supplier, or any other type of entity that receives payment for bad debts under the authority under subparagraph (A).

(2)(A) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations more expensive than semi-private accommodations, the amount taken into account for purposes of payment under this title with respect to such services may not exceed the amount that would be taken into account with respect to such services if furnished in such semi-private accommodations unless the more expensive accommodations were required for medical reasons.

(B) Where a provider of services which has an agreement in effect under this title furnishes to an individual items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under part A or part B, as the case may be, the Secretary shall take into account for purposes of payment to such provider of services only the items or services with respect to which such payment may be made.

(3) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations other than, but not more expensive than, semi-private accommodations and the use of such other accommodations rather than semi-private accommodations was neither at the request of the patient nor for a reason which the Secretary determines is consistent with the purposes of this title, the amount of the payment with respect to such bed and board under part A shall be the amount otherwise payable under this title for such bed and board furnished in semi-private accommodations minus the difference between the charge customarily made by the hospital or skilled nursing facility for bed and board in semi-private accommodations and the charge customarily made by it for bed and board in the accommodations furnished.

(4) If a provider of services furnishes items or services to an individual which are in excess of or more expensive than the items or services determined to be necessary in the efficient delivery of needed health services and charges are imposed for such more expensive items or services under the authority granted in section 1866(a)(2)(B)(ii), the amount of payment with respect to such items or services otherwise due such provider in any fiscal period shall be reduced to the extent that such payment plus such charges exceed the cost actually incurred for such items or services in the fiscal period in which such charges are imposed.

(5)(A) Where physical therapy services, occupational therapy services, speech therapy services, or other therapy services or services of other health-related personnel (other than physicians) are furnished under an arrangement with a provider of services or other organization, specified in the first sentence of subsection (p) (including through the operation of subsection (g)) the amount included in any payment to such provider or other organization under this title as the reasonable cost of such services (as furnished under such arrangements) shall not exceed an amount equal to the salary which would reasonably have been paid for such services (together with any additional costs that would have been incurred by the provider or other organization) to the person performing them if they had been performed in an employment relationship with such provider or other organization (rather than under such arrangement) plus the cost of such other expenses (including a reasonable allowance for traveltime and other reasonable types of expense related to any differences in acceptable methods of organization for the provision of such therapy) incurred by such person, as the Secretary may in regulations determine to be appropriate.

(B) Notwithstanding the provisions of subparagraph (A), if a provider of services or other organization specified in the first sentence of section 1861(p) requires the services of a therapist on a limited part-time basis, or only to perform intermittent services, the Secretary may make payment on the basis of a reasonable rate per unit of service, even though such rate is greater per unit of time than salary related amounts, where he finds that such greater payment is, in the aggregate, less than the amount that would have been paid if such organization had employed a therapist on a full- or part-time salary basis.

(6) For purposes of this subsection, the term "semi-private accommodations" means two-bed, three-bed, or four-bed accommodations.

(7)(A) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122.

(B) For further limitations on reasonable cost and determination of payment amounts for operating costs of inpatient hospital services and waivers for certain States, see section 1886.

(C) For provisions restricting payment for provider-based physicians' services and for payments under certain percentage arrangements, see section 1887.

(D) For further limitations on reasonable cost and determination of payment amounts for routine service costs of skilled nursing facilities, see subsections (a) through (c) of section 1888.

(8) ITEMS UNRELATED TO PATIENT CARE.—Reasonable costs do not include costs for the following—

(i) entertainment, including tickets to sporting and other entertainment events;
(ii) gifts or donations;
(iii) personal use of motor vehicles;
(iv) costs for fines and penalties resulting from violations of Federal, State, or local laws; and
(v) education expenses for spouses or other dependents of providers of services, their employees or contractors.

Arrangements for Certain Services

(w)(1) The term "arrangements" is limited to arrangements under which receipt of payment by the hospital, critical access hospital, skilled nursing facility, home health agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.

(2) Utilization review activities conducted, in accordance with the requirements of the program established under part B of title XI of the Social Security Act with respect to services furnished by a hospital or critical access hospital to patients insured under part A of this title or entitled to have payment made for such services under part B of this title or under a State plan approved under title XIX, by a quality improvement organization designated for the area in which such hospital or critical access hospital is located shall be deemed to have been conducted pursuant to arrangements between such hospital or critical access hospital and such organization under which such hospital or critical access hospital is obligated to pay to such organization, as a condition of receiving payment for hospital or critical access hospital services so furnished under this part or under such a State plan, such amount as is reasonably incurred and requested (as determined under regulations of the Secretary) by such organization in conducting such review activities with respect to services furnished by such hospital or critical access hospital to such patients.

State and United States

(x) The terms "State" and "United States" have the meaning given to them by subsections (h) and (i), respectively, of section 210.

Extended Care in Religious Nonmedical Health Care Institutions

(y)(1) The term "skilled nursing facility" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only (except for purposes of subsection (a)(2)) with respect to items and services ordinarily furnished by such an institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise ap-

plicable) as may be provided in regulations consistent with section 1821.

(2) Notwithstanding any other provision of this title, payment under part A may not be made for services furnished an individual in a skilled nursing facility to which paragraph (1) applies unless such individual elects, in accordance with regulations, for a spell of illness to have such services treated as post-hospital extended care services for purposes of such part; and payment under part A may not be made for post-hospital extended care services—

(A) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) applies after—

(i) such services have been furnished to him in such a facility for 30 days during such spell, or

(ii) such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph does not apply; or

(B) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) does not apply after such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph applies.

(3) The amount payable under part A for post-hospital extended care services furnished an individual during any spell of illness in a skilled nursing facility to which paragraph (1) applies shall be reduced by a coinsurance amount equal to one-eighth of the inpatient hospital deductible for each day before the 31st day on which he is furnished such services in such a facility during such spell (and the reduction under this paragraph shall be in lieu of any reduction under section 1813(a)(3)).

(4) For purposes of subsection (i), the determination of whether services furnished by or in an institution described in paragraph (1) constitute post-hospital extended care services shall be made in accordance with and subject to such conditions, limitations, and requirements as may be provided in regulations.

Institutional Planning

(z) An overall plan and budget of a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, or home health agency shall be considered sufficient if it—

(1) provides for an annual operating budget which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items (except that nothing in this paragraph shall require that there be prepared, in connection with any budget, an item-by-item identification of the components of each type of anticipated expenditure or income);

(2)(A) provides for a capital expenditures plan for at least a 3-year period (including the year to which the operating budget described in paragraph (1) is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure in excess of $600,000 (or such lesser amount as may be established by the State under section 1122(g)(1) in which the hospital is located) related to the acquisition of land, the improvement of land, buildings, and equipment, and the replacement, modernization,

and expansion of the buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(B) provides that such plan is submitted to the agency designated under section 1122(b), or if no such agency is designated, to the appropriate health planning agency in the State (but this subparagraph shall not apply in the case of a facility exempt from review under section 1122 by reason of section 1122(j));

(3) provides for review and updating at least annually; and

(4) is prepared, under the direction of the governing body of the institution or agency, by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the institution or agency.

Rural Health Clinic Services and Federally Qualified Health Center Services

(aa)(1) The term "rural health clinic services" means —

(A) physicians' services and such services and supplies as are covered under section 1861(s)(2)(A) if furnished as an incident to a physician's professional service and items and services described in section 1861(s)(10),

(B) such services furnished by a physician assistant or a nurse practitioner (as defined in paragraph (5)), by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(1)), and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician's service, and

(C) in the case of a rural health clinic located in an area in which there exists a shortage of home health agencies, part-time or intermittent nursing care and related medical supplies (other than drugs and biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound individual under a written plan of treatment (i) established and periodically reviewed by a physician described in paragraph (2)(B), or (ii) established by a nurse practitioner or physician assistant and periodically reviewed and approved by a physician described in paragraph (2)(B),

when furnished to an individual as an outpatient of a rural health clinic.

(2) The term "rural health clinic" means a facility which —

(A) is primarily engaged in furnishing to outpatients services described in subparagraphs (A) and (B) of paragraph (1);

(B) in the case of a facility which is not a physician-directed clinic, has an arrangement (consistent with the provisions of State and local law relative to the practice, performance, and delivery of health services) with one or more physicians (as defined in subsection (r)(1)) under which provision is made for the periodic review by such physicians of covered services furnished by physician assistants and nurse practitioners, the supervision and guidance by such physicians of physician assistants and nurse practitioners, the preparation by such physicians of such medical orders for care and treatment of clinic patients as may be necessary, and the availability of such phy-

sicians for such referral of and consultation for patients as is necessary and for advice and assistance in the management of medical emergencies; and, in the case of a physician-directed clinic, has one or more of its staff physicians perform the activities accomplished through such an arrangement;

(C) maintains clinical records on all patients;

(D) has arrangements with one or more hospitals, having agreements in effect under section 1866, for the referral and admission of patients requiring inpatient services or such diagnostic or other specialized services as are not available at the clinic;

(E) has written policies, which are developed with the advice of (and with provision for review of such policies from time to time by) a group of professional personnel, including one or more physicians and one or more physician assistants or nurse practitioners, to govern those services described in paragraph (1) which it furnishes;

(F) has a physician, physician assistant, or nurse practitioner responsible for the execution of policies described in subparagraph (E) and relating to the provision of the clinic's services;

(G) directly provides routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the Secretary, and has prompt access to additional diagnostic services from facilities meeting requirements under this title;

(H) in compliance with State and Federal law, has available for administering to patients of the clinic at least such drugs and biologicals as are determined by the Secretary to be necessary for the treatment of emergency cases (as defined in regulations) and has appropriate procedures or arrangements for storing, administering, and dispensing any drugs and biologicals;

(I) has a quality assessment and performance improvement program, and appropriate procedures for review of utilization of clinic services, as the Secretary may specify;

(J) has a nurse practitioner, a physician assistant, or a certified nurse-midwife (as defined in subsection (gg)) available to furnish patient care services not less than 50 percent of the time the clinic operates; and

(K) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic.

For the purposes of this title, such term includes only a facility which (i) is located in an area that is not an urbanized area (as defined by the Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners (as determined by the Secretary), and that, within the previous 4-year period, has been designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services or designated by the Secretary either (I) as an area with a shortage of personal health services under section 330(b)(3) or 1302(7) of the Public Health Service Act, (II) as a health professional shortage area described in section 332(a)(1)(A) of that Act because of its shortage of primary medical care manpower, (III) as a high impact area described in section 329(a)(5) of that Act, of (IV)

as an area which includes a population group which the Secretary determines has a health manpower shortage under section 332(a)(1)(B) of that Act, (ii) has filed an agreement with the Secretary by which it agrees not to charge any individual or other person for items or services for which such individual is entitled to have payment made under this title, except for the amount of any deductible or coinsurance amount imposed with respect to such items or services (not in excess of the amount customarily charged for such items and services by such clinic), pursuant to subsections (a) and (b) of section 1833, (iii) employs a physician assistant or nurse practitioner, and (iv) is not a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. A facility that is in operation and qualifies as a rural health clinic under this title or title XIX and that subsequently fails to satisfy the requirement of clause (i) shall be considered, for purposes of this title and title XIX, as still satisfying the requirement of such clause if it is determined, in accordance with criteria established by the Secretary in regulations, to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinic. If a State agency has determined under section 1864(a) that a facility is a rural health clinic and the facility has applied to the Secretary for approval as such a clinic, the Secretary shall notify the facility of the Secretary's approval or disapproval not later than 60 days after the date of the State agency determination or the application (whichever is later).

(3) The term "Federally qualified health center services" means—

(A) services of the type described in subparagraphs (A) through (C) of paragraph (1) and preventive services (as defined in section 1861(ddd)(3)); and

(B) preventive primary health services that a center is required to provide under section 330 of the Public Health Service Act,

when furnished to an individual as an outpatient of a Federally qualified health center by the center or by a health care professional under contract with the center and, for this purpose, any reference to a rural health clinic or a physician described in paragraph (2)(B) is deemed a reference to a Federally qualified health center or a physician at the center, respectively.

(4) The term "Federally qualified health center" means an entity which—

(A)(i) is receiving a grant under section 330 of the Public Health Service Act, or

(ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under section 330 of such Act;

(B) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant;

(C) was treated by the Secretary, for purposes of part B, as a comprehensive Federally funded health center as of January 1, 1990; or

(D) is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determina-

tion Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(5)(A) The term "physician assistant" and the term "nurse practitioner" mean, for purposes of this title, a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

(B) The term "clinical nurse specialist" means, for purposes of this title, an individual who—

(i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(ii) holds a master's degree in a defined clinical area of nursing from an accredited educational institution.

(6) The term "collaboration" means a process in which a nurse practitioner works with a physician to deliver health care services within the scope of the practitioner's professional expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as defined by the law of the State in which the services are performed.

(7)(A) The Secretary shall waive for a 1-year period the requirements of paragraph (2) that a rural health clinic employ a physician assistant, nurse practitioner or certified nurse midwife or that such clinic require such providers to furnish services at least 50 percent of the time that the clinic operates for any facility that requests such waiver if the facility demonstrates that the facility has been unable, despite reasonable efforts, to hire a physician assistant, nurse practitioner, or certified nurse-midwife in the previous 90-day period.

(B) The Secretary may not grant such a waiver under subparagraph (A) to a facility if the request for the waiver is made less than 6 months after the date of the expiration of any previous such waiver for the facility, or if the facility has not yet been determined to meet the requirements (including subparagraph (J) of the first sentence of paragraph (2)) of a rural health clinic.

(C) A waiver which is requested under this paragraph shall be deemed granted unless such request is denied by the Secretary within 60 days after the date such request is received.

Services of a Certified Registered Nurse Anesthetist

(bb)(1) The term "services of a certified registered nurse anesthetist" means anesthesia services and related care furnished by a certified registered nurse anesthetist (as defined in paragraph (2)) which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished.

(2) The term "certified registered nurse anesthetist" means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the

certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

Comprehensive Outpatient Rehabilitation Facility Services

(cc)(1) The term "comprehensive outpatient rehabilitation facility services" means the following items and services furnished by a physician or other qualified professional personnel (as defined in regulations by the Secretary) to an individual who is an outpatient of a comprehensive outpatient rehabilitation facility under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician—

(A) physicians' services;

(B) physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy;

(C) prosthetic and orthotic devices, including testing, fitting, or training in the use of prosthetic and orthotic devices;

(D) social and psychological services;

(E) nursing care provided by or under the supervision of a registered professional nurse;

(F) drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered;

(G) supplies and durable medical equipment; and

(H) such other items and services as are medically necessary for the rehabilitation of the patient and are ordinarily furnished by comprehensive outpatient rehabilitation facilities,

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital. In the case of physical therapy, occupational therapy, and speech pathology services, there shall be no requirement that the item or service be furnished at any single fixed location if the item or service is furnished pursuant to such plan and payments are not otherwise made for the item or service under this title.

(2) The term "comprehensive outpatient rehabilitation facility" means a facility which—

(A) is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons;

(B) provides at least the following comprehensive outpatient rehabilitation services: (i) physicians' services (rendered by physicians, as defined in section 1861(r)(1), who are available at the facility on a full- or part-time basis); (ii) physical therapy; and (iii) social or psychological services;

(C) maintains clinical records on all patients;

(D) has policies established by a group of professional personnel (associated with the facility), including one or more physicians defined in subsection (r)(1) to govern the comprehensive outpatient rehabilitation services it furnishes, and provides for the carrying out of such policies by a full- or part-time physician referred to in subparagraph (B)(i);

(E) has a requirement that every patient must be under the care of a physician;

(F) in the case of a facility in any State in which State or applicable local law provides for the licensing of facilities of this nature (i) is licensed pursuant to such law, or (ii) is ap-

proved by the agency of such State or locality, responsible for licensing facilities of this nature, as meeting the standards established for such licensing;

(G) has in effect a utilization review plan in accordance with regulations prescribed by the Secretary;

(H) has in effect an overall plan and budget that meets the requirements of subsection (z);

(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000; and

(J) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.

The Secretary may waive the requirement of a surety bond under subparagraph (I) in the case of a facility that provides a comparable surety bond under State law.

Hospice Care; Hospice Program

(dd)(1) The term "hospice care" means the following items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director (and by the interdisciplinary group described in paragraph (2)(B)) of the program—

(A) nursing care provided by or under the supervision of a registered professional nurse,

(B) physical or occupational therapy, or speech-language pathology services,

(C) medical social services under the direction of a physician,

(D)(i) services of a home health aide who has successfully completed a training program approved by the Secretary and (ii) homemaker services,

(E) medical supplies (including drugs and biologicals) and the use of medical appliances, while under such a plan,

(F) physicians' services,

(G) short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days,

(H) counseling (including dietary counseling) with respect to care of the terminally ill individual and adjustment to his death, and

(I) any other item or service which is specified in the plan and for which payment may otherwise be made under this title.

The care and services described in subparagraphs (A) and (D) may be provided on a 24-hour, continuous basis only during periods of crisis (meeting criteria established by the Secretary) and only as necessary to maintain the terminally ill individual at home.

(2) The term "hospice program" means a public agency or private organization (or a subdivision thereof) which—

(A)(i) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals and services described in section 1812(a)(5),

(ii) provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the agency or organization, except that—

(I) the agency or organization must routinely provide directly substantially all of each of the services described in subparagraphs (A), (C), and (H) of paragraph (1), except as otherwise provided in paragraph (5), and

(II) in the case of other services described in paragraph (1) which are not provided directly by the agency or organization, the agency or organization must maintain professional management responsibility for all such services furnished to an individual, regardless of the location or facility in which such services are furnished; and

(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G) provided in any 12-month period to individuals who have an election in effect under section 1812(d) with respect to that agency or organization does not exceed 20 percent of the aggregate number of days during that period on which such elections for such individuals are in effect;

(B) has an interdisciplinary group of personnel which—

(i) includes at least—

(I) one physician (as defined in subsection (r)(1)),

(II) one registered professional nurse, and

(III) one social worker,

employed by or, in the case of a physician described in subclause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,

(ii) provides (or supervises the provision of) the care and services described in paragraph (1), and

(iii) establishes the policies governing the provision of such care and services;

(C) maintains central clinical records on all patients;

(D) does not discontinue the hospice care it provides with respect to a patient because of the inability of the patient to pay for such care;

(E)(i) utilizes volunteers in its provision of care and services in accordance with standards set by the Secretary, which standards shall ensure a continuing level of effort to utilize such volunteers, and (ii) maintains records on the use of these volunteers and the cost savings and expansion of care and services achieved through the use of these volunteers;

(F) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, is licensed pursuant to such law; and

(G) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(3)(A) An individual is considered to be "terminally ill" if the individual has a medical prognosis that the individual's life expectancy is 6 months or less.

(B) The term "attending physician" means, with respect to an individual, the physician (as defined in subsection (r)(1)), the nurse practitioner (as defined in subsection (aa)(5)), or the physician assistant (as defined in such subsection), who may be employed by a hospice program, whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.

(4)(A) An entity which is certified as a provider of services other than a hospice program shall be considered, for purposes of certification as a hospice program, to have met any requirements under paragraph (2) which are also the same requirements for certification as such other type of provider. The Secretary shall coordinate surveys for determining certification under this title so as to provide, to the extent feasible, for simultaneous surveys of an entity which seeks to be certified as a hospice program and as a provider of services of another type.

(B) Any entity which is certified as a hospice program and as a provider of another type shall have separate provider agreements under section 1866 and shall file separate cost reports with respect to costs incurred in providing hospice care and in providing other services and items under this title.

[(C) Any entity that is certified as a hospice program shall be subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months beginning 6 months after the date of the enactment of this subparagraph and ending September 30, 2025.]

(5)(A) The Secretary may waive the requirements of paragraph (2)(A)(ii)(I) for an agency or organization with respect to all or part of the nursing care described in paragraph (1)(A) if such agency or organization—

(i) is located in an area which is not an urbanized area (as defined by the Bureau of the Census);

(ii) was in operation on or before January 1, 1983; and

(iii) has demonstrated a good faith effort (as determined by the Secretary) to hire a sufficient number of nurses to provide such nursing care directly.

(B) Any waiver, which is in such form and containing such information as the Secretary may require and which is requested by an agency or organization under subparagraph (A) or (C), shall be deemed to be granted unless such request is denied by the Secretary within 60 days after the date such request is received by the Secretary. The granting of a waiver under subparagraph (A) or (C) shall not preclude the granting of any subsequent waiver request should such a waiver again become necessary.

(C) The Secretary may waive the requirements of paragraph (2)(A)(i) and (2)(A)(ii) for an agency or organization with respect to

the services described in paragraph (1)(B) and, with respect to dietary counseling, paragraph (1)(H), if such agency or organization—

(i) is located in an area which is not an urbanized area (as defined by the Bureau of Census), and

(ii) demonstrates to the satisfaction of the Secretary that the agency or organization has been unable, despite diligent efforts, to recruit appropriate personnel.

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.

Discharge Planning Process

(ee)(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this title and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient's representative, or patient's physician.

(C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(D) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including hospice care and post-hospital extended care services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this title and that serve the area in which the patient resides and that request to be listed by the hospital as available and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities

that participate in the program under this title and that serve the area in which the patient resides.

(E) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(F) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, social worker, or other appropriately qualified personnel.

(H) Consistent with section 1802, the discharge plan shall—

(i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

(ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1866(a)(1)(S)) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization—

(A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

(B) notwithstanding subparagraph (H)(i), the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

Partial Hospitalization Services

(ff)(1) The term "partial hospitalization services" means the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.

(2) The items and services described in this paragraph are—

(A) individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law),

(B) occupational therapy requiring the skills of a qualified occupational therapist,

(C) services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients,

(D) drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered),

(E) individualized activity therapies that are not primarily recreational or diversionary,

(F) family counseling (the primary purpose of which is treatment of the individual's condition),

(G) patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment),

(H) diagnostic services, and

(I) such other items and services as the Secretary may provide (but in no event to include meals and transportation);

that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish (taking into account accepted norms of medical practice and the reasonable expectation of patient improvement).

(3)(A) A program described in this paragraph is a program which is furnished by a hospital to its outpatients or by a community mental health center (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.

(B) For purposes of subparagraph (A), the term "community mental health center" means an entity that—

(i)(I) provides the mental health services described in section 1913(c)(1) of the Public Health Service Act; or

(II) in the case of an entity operating in a State that by law precludes the entity from providing itself the service described in subparagraph (E) of such section, provides for such service by contract with an approved organization or entity (as determined by the Secretary);

(ii) meets applicable licensing or certification requirements for community mental health centers in the State in which it is located;

(iii) provides at least 40 percent of its services to individuals who are not eligible for benefits under this title; and

(iv) meets such additional conditions as the Secretary shall specify to ensure (I) the health and safety of individuals being furnished such services, (II) the effective and efficient furnishing of such services, and (III) the compliance of such entity with the criteria described in section 1931(c)(1) of the Public Health Service Act.

Certified Nurse-Midwife Services

(gg)(1) The term "certified nurse-midwife services" means such services furnished by a certified nurse-midwife (as defined in paragraph (2)) and such services and supplies furnished as an incident to the nurse-midwife's service which the certified nurse-midwife is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be

covered if furnished by a physician or as an incident to a physicians' service.

(2) The term "certified nurse-midwife" means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

Clinical Social Worker; Clinical Social Worker Services

(hh)(1) The term "clinical social worker" means an individual who—

(A) possesses a master's or doctor's degree in social work;

(B) after obtaining such degree has performed at least 2 years of supervised clinical social work; and

(C)(i) is licensed or certified as a clinical social worker by the State in which the services are performed, or

(ii) in the case of an individual in a State which does not provide for licensure or certification—

(I) has completed at least 2 years or 3,000 hours of post-master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting (as determined by the Secretary), and

(II) meets such other criteria as the Secretary establishes.

(2) The term "clinical social worker services" means services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.

Qualified Psychologist Services

(ii) The term "qualified psychologist services" means such services and such services and supplies furnished as an incident to his service furnished by a clinical psychologist (as defined by the Secretary) which the psychologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physician's service.

Screening Mammography

(jj) The term "screening mammography" means a radiologic procedure provided to a woman for the purpose of early detection of breast cancer and includes a physician's interpretation of the results of the procedure.

Covered Osteoporosis Drug

(kk) The term "covered osteoporosis drug" means an injectable drug approved for the treatment of post-menopausal osteoporosis provided to an individual by a home health agency if, in accordance with regulations promulgated by the Secretary—

(1) the individual's attending physician certifies that the individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to learn the skills needed to self-administer such drug or is otherwise physically or mentally incapable of self-administering such drug; and

(2) the individual is confined to the individual's home (except when receiving items and services referred to in subsection (m)(7)).

Speech-Language Pathology Services; Audiology Services

(ll)(1) The term "speech-language pathology services" means such speech, language, and related function assessment and rehabilitation services furnished by a qualified speech-language pathologist as the speech-language pathologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician.

(2) The term "outpatient speech-language pathology services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that in applying such subsection—

(A) "speech-language pathology" shall be substituted for "physical therapy" each place it appears; and

(B) "speech-language pathologist" shall be substituted for "physical therapist" each place it appears.

(3) The term "audiology services" means such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), as would otherwise be covered if furnished by a physician.

(4) In this subsection:

(A) The term "qualified speech-language pathologist" means an individual with a master's or doctoral degree in speech-language pathology who—

(i) is licensed as a speech-language pathologist by the State in which the individual furnishes such services, or

(ii) in the case of an individual who furnishes services in a State which does not license speech-language pathologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed a national examination in speech-language pathology approved by the Secretary.

(B) The term "qualified audiologist" means an individual with a master's or doctoral degree in audiology who—

(i) is licensed as an audiologist by the State in which the individual furnishes such services, or

(ii) in the case of an individual who furnishes services in a State which does not license audiologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time audiology services after obtaining a master's or doctoral degree in audiology or a related field, and successfully completed a national examination in audiology approved by the Secretary.

Critical Access Hospital; Critical Access Hospital Services

(mm)(1) The term "critical access hospital" means a facility certified by the Secretary as a critical access hospital under section 1820(e).

(2) The term "inpatient critical access hospital services" means items and services, furnished to an inpatient of a critical access hospital by such facility, that would be inpatient hospital services if furnished to an inpatient of a hospital by a hospital.

(3) The term "outpatient critical access hospital services" means medical and other health services furnished by a critical access hospital on an outpatient basis.

Screening Pap Smear; Screening Pelvic Exam

(nn)(1) The term "screening pap smear" means a diagnostic laboratory test consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and includes a physician's interpretation of the results of the test, if the individual involved has not had such a test during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3).

(2) The term "screening pelvic exam" means a pelvic examination provided to a woman if the woman involved has not had such an examination during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3), and includes a clinical breast examination.

(3) A woman described in this paragraph is a woman who—

(A) is of childbearing age and has had a test described in this subsection during any of the preceding 3 years that indicated the presence of cervical or vaginal cancer or other abnormality; or

(B) is at high risk of developing cervical or vaginal cancer (as determined pursuant to factors identified by the Secretary).

Prostate Cancer Screening Tests

(oo)(1) The term "prostate cancer screening test" means a test that consists of any (or all) of the procedures described in paragraph (2) provided for the purpose of early detection of prostate cancer to a man over 50 years of age who has not had such a test during the preceding year.

(2) The procedures described in this paragraph are as follows:

(A) A digital rectal examination.

(B) A prostate-specific antigen blood test.

(C) For years beginning after 2002, such other procedures as the Secretary finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and such other factors as the Secretary considers appropriate.

Colorectal Cancer Screening Tests

(pp)(1) The term "colorectal cancer screening test" means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:

(A) Screening fecal-occult blood test.

(B) Screening flexible sigmoidoscopy.

(C) Screening colonoscopy.

(D) Such other tests or procedures, and modifications to tests and procedures under this subsection, with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) An "individual at high risk for colorectal cancer" is an individual who, because of family history, prior experience of cancer or precursor neoplastic polyps, a history of chronic digestive disease condition (including inflammatory bowel disease, Crohn's Disease, or ulcerative colitis), the presence of any appropriate recognized gene markers for colorectal cancer, or other predisposing factors, faces a high risk for colorectal cancer.

Diabetes Outpatient Self-Management Training Services

(qq)(1) The term "diabetes outpatient self-management training services" means educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.

(2) In paragraph (1)—

(A) a "certified provider" is a physician, or other individual or entity designated by the Secretary, that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this title; and

(B) a physician, or such other individual or entity, meets the quality standards described in this paragraph if the physician, or individual or entity, meets quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in

the establishment of standards by such Board, or is recognized by an organization that represents individuals (including individuals under this title) with diabetes as meeting standards for furnishing the services.

Bone Mass Measurement

(rr)(1) The term "bone mass measurement" means a radiologic or radioisotopic procedure or other procedure approved by the Food and Drug Administration performed on a qualified individual (as defined in paragraph (2)) for the purpose of identifying bone mass or detecting bone loss or determining bone quality, and includes a physician's interpretation of the results of the procedure.

(2) For purposes of this subsection, the term "qualified individual" means an individual who is (in accordance with regulations prescribed by the Secretary)—

(A) an estrogen-deficient woman at clinical risk for osteoporosis;

(B) an individual with vertebral abnormalities;

(C) an individual receiving long-term glucocorticoid steroid therapy;

(D) an individual with primary hyperparathyroidism; or

(E) an individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy.

(3) The Secretary shall establish such standards regarding the frequency with which a qualified individual shall be eligible to be provided benefits for bone mass measurement under this title.

Religious Nonmedical Health Care Institution

(ss)(1) The term "religious nonmedical health care institution" means an institution that—

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection (a) of such section;

(B) is lawfully operated under all applicable Federal, State, and local laws and regulations;

(C) provides only nonmedical nursing items and services exclusively to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs;

(D) provides such nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of such patients;

(E) provides such nonmedical items and services to inpatients on a 24-hour basis;

(F) on the basis of its religious beliefs, does not provide through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;

(G)(i) is not owned by, under common ownership with, or has an ownership interest in, a provider of medical treatment or services;

(ii) is not affiliated with—

(I) a provider of medical treatment or services, or

(II) an individual who has an ownership interest in a provider of medical treatment or services;

(H) has in effect a utilization review plan which—

(i) provides for the review of admissions to the institution, of the duration of stays therein, of cases of continuous extended duration, and of the items and services furnished by the institution,

(ii) requires that such reviews be made by an appropriate committee of the institution that includes the individuals responsible for overall administration and for supervision of nursing personnel at the institution,

(iii) provides that records be maintained of the meetings, decisions, and actions of such committee, and

(iv) meets such other requirements as the Secretary finds necessary to establish an effective utilization review plan;

(I) provides the Secretary with such information as the Secretary may require to implement section 1821, including information relating to quality of care and coverage determinations; and

(J) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

(2) To the extent that the Secretary finds that the accreditation of an institution by a State, regional, or national agency or association provides reasonable assurances that any or all of the requirements of paragraph (1) are met or exceeded, the Secretary may treat such institution as meeting the condition or conditions with respect to which the Secretary made such finding.

(3)(A)(i) In administering this subsection and section 1821, the Secretary shall not require any patient of a religious nonmedical health care institution to undergo medical screening, examination, diagnosis, prognosis, or treatment or to accept any other medical health care service, if such patient (or legal representative of the patient) objects thereto on religious grounds.

(ii) Clause (i) shall not be construed as preventing the Secretary from requiring under section 1821(a)(2) the provision of sufficient information regarding an individual's condition as a condition for receipt of benefits under part A for services provided in such an institution.

(B)(i) In administering this subsection and section 1821, the Secretary shall not subject a religious nonmedical health care institution or its personnel to any medical supervision, regulation, or control, insofar as such supervision, regulation, or control would be contrary to the religious beliefs observed by the institution or such personnel.

(ii) Clause (i) shall not be construed as preventing the Secretary from reviewing items and services billed by the institution to the extent the Secretary determines such review to be necessary to determine whether such items and services were not covered under part A, are excessive, or are fraudulent.

(4)(A) For purposes of paragraph (1)(G)(i), an ownership interest of less than 5 percent shall not be taken into account.

(B) For purposes of paragraph (1)(G)(ii), none of the following shall be considered to create an affiliation:

(i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of a religious nonmedical health care institution.

(ii) An individual who is a director, trustee, officer, employee, or staff member of a religious nonmedical health care institution having a family relationship with an individual who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(iii) An individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and religious nonmedical health care institutions.

Post-Institutional Home Health Services; Home Health Spell of Illness

(tt)(1) The term "post-institutional home health services" means home health services furnished to an individual—

(A) after discharge from a hospital or critical access hospital in which the individual was an inpatient for not less than 3 consecutive days before such discharge if such home health services were initiated within 14 days after the date of such discharge; or

(B) after discharge from a skilled nursing facility in which the individual was provided post-hospital extended care services if such home health services were initiated within 14 days after the date of such discharge.

(2) The term "home health spell of illness" with respect to any individual means a period of consecutive days—

(A) beginning with the first day (not included in a previous home health spell of illness) (i) on which such individual is furnished post-institutional home health services, and (ii) which occurs in a month for which the individual is entitled to benefits under part A, and

(B) ending with the close of the first period of 60 consecutive days thereafter on each of which the individual is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1819(a)(1) or subsection (y)(1) nor provided home health services.

Screening for Glaucoma

(uu) The term "screening for glaucoma" means a dilated eye examination with an intraocular pressure measurement, and a direct ophthalmoscopy or a slit-lamp biomicroscopic examination for the early detection of glaucoma which is furnished by or under the direct supervision of an optometrist or ophthalmologist who is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished, as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service, if the individual involved has not had such an examination in the preceding year.

Medical Nutrition Therapy Services; Registered Dietitian or Nutrition Professional

(vv)(1) The term "medical nutrition therapy services" means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).

(2) Subject to paragraph (3), the term "registered dietitian or nutrition professional" means an individual who—

(A) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose;

(B) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

(C)(i) is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed; or

(ii) in the case of an individual in a State that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes.

(3) Subparagraphs (A) and (B) of paragraph (2) shall not apply in the case of an individual who, as of the date of the enactment of this subsection, is licensed or certified as a dietitian or nutrition professional by the State in which medical nutrition therapy services are performed.

Initial Preventive Physical Examination

(ww)(1) The term "initial preventive physical examination" means physicians' services consisting of a physical examination (including measurement of height, weight body mass index,, and blood pressure) with the goal of health promotion and disease detection and includes education, counseling, and referral with respect to screening and other preventive services described in paragraph (2), end-of-life planning (as defined in paragraph (3)) upon the agreement with the individual, and the furnishing of a review of any current opioid prescriptions (as defined in paragraph (4)), but does not include clinical laboratory tests.

(2) The screening and other preventive services described in this paragraph include the following:

(A) Pneumococcal, influenza, and hepatitis B vaccine and administration under subsection (s)(10).

(B) Screening mammography as defined in subsection (jj).

(C) Screening pap smear and screening pelvic exam as defined in subsection (nn).

(D) Prostate cancer screening tests as defined in subsection (oo).

(E) Colorectal cancer screening tests as defined in subsection (pp).

(F) Diabetes outpatient self-management training services as defined in subsection (qq)(1).

(G) Bone mass measurement as defined in subsection (rr).

(H) Screening for glaucoma as defined in subsection (uu).

(I) Medical nutrition therapy services as defined in subsection (vv).

(J) Cardiovascular screening blood tests as defined in subsection (xx)(1).

(K) Diabetes screening tests as defined in subsection (yy).

(L) Ultrasound screening for abdominal aortic aneurysm as defined in section 1861(bbb).

(M) An electrocardiogram.

(N) Screening for potential substance use disorders.

(O) Additional preventive services (as defined in subsection (ddd)(1)).

(3) For purposes of paragraph (1), the term "end-of-life planning" means verbal or written information regarding—

(A) an individual's ability to prepare an advance directive in the case that an injury or illness causes the individual to be unable to make health care decisions; and

(B) whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

(4) For purposes of paragraph (1), the term "a review of any current opioid prescriptions" means, with respect to an individual determined to have a current prescription for opioids—

(A) a review of the potential risk factors to the individual for opioid use disorder;

(B) an evaluation of the individual's severity of pain and current treatment plan;

(C) the provision of information on non-opioid treatment options; and

(D) a referral to a specialist, as appropriate.

Cardiovascular Screening Blood Test

(xx)(1) The term "cardiovascular screening blood test" means a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) that tests for the following:

(A) Cholesterol levels and other lipid or triglyceride levels.

(B) Such other indications associated with the presence of, or an elevated risk for, cardiovascular disease as the Secretary may approve for all individuals (or for some individuals determined by the Secretary to be at risk for cardiovascular disease), including indications measured by noninvasive testing.

The Secretary may not approve an indication under subparagraph (B) for any individual unless a blood test for such is recommended by the United States Preventive Services Task Force.

(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency for each type of cardiovascular screening blood tests, except that such frequency may not be more often than once every 2 years.

Diabetes Screening Tests

(yy)(1) The term "diabetes screening tests" means testing furnished to an individual at risk for diabetes (as defined in paragraph (2)) for the purpose of early detection of diabetes, including—

(A) a fasting plasma glucose test; and

(B) such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) For purposes of paragraph (1), the term "individual at risk for diabetes" means an individual who has any of the following risk factors for diabetes:

(A) Hypertension.

(B) Dyslipidemia.

(C) Obesity, defined as a body mass index greater than or equal to 30 kg/m^2.

(D) Previous identification of an elevated impaired fasting glucose.

(E) Previous identification of impaired glucose tolerance.

(F) A risk factor consisting of at least 2 of the following characteristics:

(i) Overweight, defined as a body mass index greater than 25, but less than 30, kg/m^2.

(ii) A family history of diabetes.

(iii) A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

(iv) 65 years of age or older.

(3) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

Intravenous Immune Globulin

(zz) The term "intravenous immune globulin" means an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient's home is medically appropriate.

Extended Care in Religious Nonmedical Health Care Institutions

(aaa)(1) The term "home health agency" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such an institution to individuals in their homes, and that are comparable to items and services furnished to individuals by a home health agency that is not religious nonmedical health care institution.

(2)(A) Subject to subparagraphs (B), payment may be made with respect to services provided by such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821.

(B) Notwithstanding any other provision of this title, payment may not be made under subparagraph (A)—

(i) in a year insofar as such payments exceed $700,000; and

(ii) after December 31, 2006.

Ultrasound Screening for Abdominal Aortic Aneurysm

(bbb) The term "ultrasound screening for abdominal aortic aneurysm" means—

(1) a procedure using sound waves (or such other procedures using alternative technologies, of commensurate accuracy and cost, that the Secretary may specify) provided for the early detection of abdominal aortic aneurysm; and

(2) includes a physician's interpretation of the results of the procedure.

Long-Term Care Hospital

(ccc) The term "long-term care hospital" means a hospital which—

(1) is primarily engaged in providing inpatient services, by or under the supervision of a physician, to Medicare beneficiaries whose medically complex conditions require a long hospital stay and programs of care provided by a long-term care hospital;

(2) has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days, or meets the requirements of clause (II) of section 1886(d)(1)(B)(iv);

(3) satisfies the requirements of subsection (e); and

(4) meets the following facility criteria:

(A) the institution has a patient review process, documented in the patient medical record, that screens patients prior to admission for appropriateness of admission to a long-term care hospital, validates within 48 hours of admission that patients meet admission criteria for long-term care hospitals, regularly evaluates patients throughout their stay for continuation of care in a long-term care hospital, and assesses the available discharge options when patients no longer meet such continued stay criteria;

(B) the institution has active physician involvement with patients during their treatment through an organized medical staff, physician-directed treatment with physician on-site availability on a daily basis to review patient progress, and consulting physicians on call and capable of being at the patient's side within a moderate period of time, as determined by the Secretary; and

(C) the institution has interdisciplinary team treatment for patients, requiring interdisciplinary teams of health care professionals, including physicians, to prepare and carry out an individualized treatment plan for each patient.

Additional Preventive Services; Preventive Services

(ddd)(1) The term "additional preventive services" means services not described in subparagraph (A) or (C) of paragraph (3) that identify medical conditions or risk factors and that the Secretary determines are—

(A) reasonable and necessary for the prevention or early detection of an illness or disability;

(B) recommended with a grade of A or B by the United States Preventive Services Task Force; and

(C) appropriate for individuals entitled to benefits under part A or enrolled under part B.

(2) In making determinations under paragraph (1) regarding the coverage of a new service, the Secretary shall use the process for making national coverage determinations (as defined in section 1869(f)(1)(B)) under this title. As part of the use of such process, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination.

(3) The term "preventive services" means the following:

(A) The screening and preventive services described in subsection (ww)(2) (other than the service described in subparagraph (M) of such subsection).

(B) An initial preventive physical examination (as defined in subsection (ww)).

(C) Personalized prevention plan services (as defined in subsection (hhh)(1)).

Cardiac Rehabilitation Program; Intensive Cardiac Rehabilitation Program

(eee)(1) The term "cardiac rehabilitation program" means a program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3) under the supervision of a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)).

(2) A program described in this paragraph is a program under which—

(A) items and services under the program are delivered—

(i) in a physician's office;

(ii) in a hospital on an outpatient basis; or

(iii) in other settings determined appropriate by the Secretary;

(B) a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)) is immediately available and accessible for medical consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed; and

(C) individualized treatment is furnished under a written plan established, reviewed, and signed by a physician every 30 days that describes—

(i) the individual's diagnosis;

(ii) the type, amount, frequency, and duration of the items and services furnished under the plan; and

(iii) the goals set for the individual under the plan.

(3) The items and services described in this paragraph are—

(A) physician-prescribed exercise;

(B) cardiac risk factor modification, including education, counseling, and behavioral intervention (to the extent such education, counseling, and behavioral intervention is closely re-

lated to the individual's care and treatment and is tailored to the individual's needs);

(C) psychosocial assessment;

(D) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are—

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(4)(A) The term "intensive cardiac rehabilitation program" means a program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3) under the supervision of a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)) and has shown, in peer-reviewed published research, that it accomplished—

(i) one or more of the following:

(I) positively affected the progression of coronary heart disease; or

(II) reduced the need for coronary bypass surgery; or

(III) reduced the need for percutaneous coronary interventions; and

(ii) a statistically significant reduction in 5 or more of the following measures from their level before receipt of cardiac rehabilitation services to their level after receipt of such services:

(I) low density lipoprotein;

(II) triglycerides;

(III) body mass index;

(IV) systolic blood pressure;

(V) diastolic blood pressure; or

(VI) the need for cholesterol, blood pressure, and diabetes medications.

(B) To be eligible for an intensive cardiac rehabilitation program, an individual must have—

(i) had an acute myocardial infarction within the preceding 12 months;

(ii) had coronary bypass surgery;

(iii) stable angina pectoris;

(iv) had heart valve repair or replacement;

(v) had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;

(vi) had a heart or heart-lung transplant;

(vii) stable, chronic heart failure (defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks); or

(viii) any additional condition for which the Secretary has determined that a cardiac rehabilitation program shall

be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.

(C) An intensive cardiac rehabilitation program may be provided in a series of 72 one-hour sessions (as defined in section 1848(b)(5)), up to 6 sessions per day, over a period of up to 18 weeks.

(5) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with cardiac pathophysiology who is licensed to practice medicine in the State in which a cardiac rehabilitation program (or the intensive cardiac rehabilitation program, as the case may be) is offered—

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program.

Pulmonary Rehabilitation Program

(fff)(1) The term "pulmonary rehabilitation program" means a program (as described in subsection (eee)(2) with respect to a program under this subsection) that furnishes the items and services described in paragraph (2) under the supervision of a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)).

(2) The items and services described in this paragraph are—

(A) physician-prescribed exercise;

(B) education or training (to the extent the education or training is closely and clearly related to the individual's care and treatment and is tailored to such individual's needs);

(C) psychosocial assessment;

(D) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are—

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(3) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with respiratory pathophysiology who is licensed to practice medicine in the State in which a pulmonary rehabilitation program is offered—

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program.

Kidney Disease Education Services

(ggg)(1) The term "kidney disease education services" means educational services that are—

(A) furnished to an individual with stage IV chronic kidney disease who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant;

(B) furnished, upon the referral of the physician managing the individual's kidney condition, by a qualified person (as defined in paragraph (2)); and

(C) designed—

(i) to provide comprehensive information (consistent with the standards set under paragraph (3)) regarding—

(I) the management of comorbidities, including for purposes of delaying the need for dialysis;

(II) the prevention of uremic complications; and

(III) each option for renal replacement therapy (including hemodialysis and peritoneal dialysis at home and in-center as well as vascular access options and transplantation);

(ii) to ensure that the individual has the opportunity to actively participate in the choice of therapy; and

(iii) to be tailored to meet the needs of the individual involved.

(2)(A) The term "qualified person" means—

(i) a physician (as defined in section 1861(r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)), who furnishes services for which payment may be made under the fee schedule established under section 1848; and

(ii) a provider of services located in a rural area (as defined in section 1886(d)(2)(D)).

(B) Such term does not include a provider of services (other than a provider of services described in subparagraph (A)(ii)) or a renal dialysis facility.

(3) The Secretary shall set standards for the content of such information to be provided under paragraph (1)(C)(i) after consulting with physicians, other health professionals, health educators, professional organizations, accrediting organizations, kidney patient organizations, dialysis facilities, transplant centers, network organizations described in section 1881(c)(2), and other knowledgeable persons. To the extent possible the Secretary shall consult with persons or entities described in the previous sentence, other than a dialysis facility, that has not received industry funding from a drug or biological manufacturer or dialysis facility.

(4) No individual shall be furnished more than 6 sessions of kidney disease education services under this title.

Annual Wellness Visit

(hhh)(1) The term "personalized prevention plan services" means the creation of a plan for an individual—

(A) that includes a health risk assessment (that meets the guidelines established by the Secretary under paragraph (4)(A)) of the individual that is completed prior to or as part

of the same visit with a health professional described in paragraph (3); and

(B) that—

(i) takes into account the results of the health risk assessment; and

(ii) may contain the elements described in paragraph (2).

(2) Subject to paragraph (4)(H), the elements described in this paragraph are the following:

(A) The establishment of, or an update to, the individual's medical and family history.

(B) A list of current providers and suppliers that are regularly involved in providing medical care to the individual (including a list of all prescribed medications).

(C) A measurement of height, weight, body mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements.

(D) Detection of any cognitive impairment.

(E) The establishment of, or an update to, the following:

(i) A screening schedule for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health status, screening history, and age-appropriate preventive services covered under this title.

(ii) A list of risk factors and conditions for which primary, secondary, or tertiary prevention interventions are recommended or are underway, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under subsection (ww)(1)), and a list of treatment options and their associated risks and benefits.

(F) The furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

(G) Screening for potential substance use disorders and referral for treatment as appropriate.

(H) The furnishing of a review of any current opioid prescriptions (as defined in subsection (ww)(4)).

(I) Any other element determined appropriate by the Secretary.

(3) A health professional described in this paragraph is—

(A) a physician;

(B) a practitioner described in clause (i) of section 1842(b)(18)(C); or

(C) a medical professional (including a health educator, registered dietitian, or nutrition professional) or a team of medical professionals, as determined appropriate by the Secretary, under the supervision of a physician.

(4)(A) For purposes of paragraph (1)(A), the Secretary, not later than 1 year after the date of enactment of this subsection, shall es-

tablish publicly available guidelines for health risk assessments. Such guidelines shall be developed in consultation with relevant groups and entities and shall provide that a health risk assessment—

(i) identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of the individual; and

(ii) may be furnished—

(I) through an interactive telephonic or web-based program that meets the standards established under subparagraph (B);

(II) during an encounter with a health care professional;

(III) through community-based prevention programs; or

(IV) through any other means the Secretary determines appropriate to maximize accessibility and ease of use by beneficiaries, while ensuring the privacy of such beneficiaries.

(B) Not later than 1 year after the date of enactment of this subsection, the Secretary shall establish standards for interactive telephonic or web-based programs used to furnish health risk assessments under subparagraph (A)(ii)(I). The Secretary may utilize any health risk assessment developed under section 4004(f) of the Patient Protection and Affordable Care Act as part of the requirement to develop a personalized prevention plan to comply with this subparagraph.

(C)(i) Not later than 18 months after the date of enactment of this subsection, the Secretary shall develop and make available to the public a health risk assessment model. Such model shall meet the guidelines under subparagraph (A) and may be used to meet the requirement under paragraph (1)(A).

(ii) Any health risk assessment that meets the guidelines under subparagraph (A) and is approved by the Secretary may be used to meet the requirement under paragraph (1)(A).

(D) The Secretary may coordinate with community-based entities (including State Health Insurance Programs, Area Agencies on Aging, Aging and Disability Resource Centers, and the Administration on Aging) to—

(i) ensure that health risk assessments are accessible to beneficiaries; and

(ii) provide appropriate support for the completion of health risk assessments by beneficiaries.

(E) The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment prior to or at the same time as receiving personalized prevention plan services.

(F) To the extent practicable, the Secretary shall encourage the use of, integration with, and coordination of health information technology (including use of technology that is compatible with electronic medical records and personal health records) and may experiment with the use of personalized technology to aid in the development of self-management skills and management of and adherence to provider recommendations in order to improve the health status of beneficiaries.

(G) A beneficiary shall be eligible to receive only an initial preventive physical examination (as defined under subsection (ww)(1)) during the 12-month period after the date that the beneficiary's

coverage begins under part B and shall be eligible to receive personalized prevention plan services under this subsection each year thereafter provided that the beneficiary has not received either an initial preventive physical examination or personalized prevention plan services within the preceding 12-month period.

(H) The Secretary shall issue guidance that—

(i) identifies elements under paragraph (2) that are required to be provided to a beneficiary as part of their first visit for personalized prevention plan services; and

(ii) establishes a yearly schedule for appropriate provision of such elements thereafter.

(iii) HOME INFUSION THERAPY.—(1) The term "home infusion therapy" means the items and services described in paragraph (2) furnished by a qualified home infusion therapy supplier (as defined in paragraph (3)(D)) which are furnished in the individual's home (as defined in paragraph (3)(B)) to an individual—

(A) who is under the care of an applicable provider (as defined in paragraph (3)(A)); and

(B) with respect to whom a plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished such individual has been established by a physician (as defined in subsection (r)(1)) and is periodically reviewed by a physician (as so defined) in coordination with the furnishing of home infusion drugs (as defined in paragraph (3)(C)) under part B.

(2) The items and services described in this paragraph are the following:

(A) Professional services, including nursing services, furnished in accordance with the plan.

(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

(3) For purposes of this subsection:

(A) The term "applicable provider" means—

(i) a physician;

(ii) a nurse practitioner; and

(iii) a physician assistant.

(B) The term "home" means a place of residence used as the home of an individual (as defined for purposes of subsection (n)).

(C) The term "home infusion drug" means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:

(i) Insulin pump systems.

(ii) A self-administered drug or biological on a self-administered drug exclusion list.

(D)(i) The term "qualified home infusion therapy supplier" means a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physi-

cian, or provider or services or supplier furnishes items or services and that—

(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and

(IV) meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

(ii) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements of this subparagraph.

(jjj) OPIOID USE DISORDER TREATMENT SERVICES; OPIOID TREATMENT PROGRAM.—

(1) OPIOID USE DISORDER TREATMENT SERVICES.—The term "opioid use disorder treatment services" means items and services that are furnished by an opioid treatment program for the treatment of opioid use disorder, including—

(A) opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for use in the treatment of opioid use disorder;

(B) dispensing and administration of such medications, if applicable;

(C) substance use counseling by a professional to the extent authorized under State law to furnish such services;

(D) individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law);

(E) toxicology testing, and

(F) other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation).

(2) OPIOID TREATMENT PROGRAM.—The term "opioid treatment program" means an entity that is an opioid treatment program (as defined in section 8.2 of title 42 of the Code of Federal Regulations, or any successor regulation) that—

(A) is enrolled under section 1866(j);

(B) has in effect a certification by the Substance Abuse and Mental Health Services Administration for such a program;

(C) is accredited by an accrediting body approved by the Substance Abuse and Mental Health Services Administration; and

(D) meets such additional conditions as the Secretary may find necessary to ensure—

(i) the health and safety of individuals being furnished services under such program; and

(ii) the effective and efficient furnishing of such services.

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USE OF STATE AGENCIES TO DETERMINE COMPLIANCE BY PROVIDERS OF SERVICES WITH CONDITIONS OF PARTICIPATION

SEC. 1864. (a) The Secretary shall make an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by him for the purpose of determining whether an institution therein is a hospital or skilled nursing facility, or whether an agency therein is a home health agency, or whether an agency is a hospice program or whether a facility therein is a rural health clinic as defined in section 1861(aa)(2), a critical access hospital, as defined in section 1861(mm)(1), or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2), or whether a laboratory meets the requirements of paragraphs (16) and (17) of section 1861(s) or whether a clinic, rehabilitation agency or public health agency meets the requirements of subparagraph (A) or (B), as the case may be, of section 1861(p)(4), or whether an ambulatory surgical center meets the standards specified under section 1832(a)(2)(F)(i). To the extent that the Secretary finds it appropriate, an institution or agency which such a State (or local) agency certifies is a hospital, skilled nursing facility, rural health clinic, comprehensive outpatient rehabilitation facility, home health agency, or hospice program (as those terms are defined in section 1861) may be treated as such by the Secretary. Any State agency which has such an agreement may (subject to approval of the Secretary) furnish to a skilled nursing facility, after proper request by such facility, such specialized consultative services (which such agency is able and willing to furnish in a manner satisfactory to the Secretary) as such facility may need to meet one or more of the conditions specified in section 1819(a). Any such services furnished by a State agency shall be deemed to have been furnished pursuant to such agreement. Within 90 days following the completion of each survey of any health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary shall make public in readily available form and place, and require (in the case of skilled nursing facilities) the posting in a place readily accessible to patients (and patients' representatives), the pertinent findings of each such survey relating to the compliance of each such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization with (1) the statutory conditions of participation imposed under this title and (2) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization. Any agreement under this subsection shall provide for the appropriate

State or local agency to maintain a toll-free hotline (1) to collect, maintain, and continually update information on home health agencies *and hospice programs* located in the State or locality that are certified to participate in the program established under this title (which information shall include any significant deficiencies found with respect to patient care in the most recent certification survey conducted by a State agency or accreditation survey conducted by a private accreditation agency under section 1865 with respect to the home health agency *or the hospice program*, when that survey was completed, whether corrective actions have been taken or are planned, and the sanctions, if any, imposed under this title with respect to the agency *or the hospice program*) and (2) to receive complaints (and answer questions) with respect to home health agencies *and hospice programs* in the State or locality. Any such agreement shall provide for such State or local agency to maintain a unit for investigating such complaints that possesses enforcement authority and has access to survey and certification reports, information gathered by any private accreditation agency utilized by the Secretary under section 1865, and consumer medical records (but only with the consent of the consumer or his or her legal representative).

(b) The Secretary shall pay any such State, in advance or by way of reimbursement, as may be provided in the agreement with it (and may make adjustments in such payments on account of overpayments or underpayments previously made), for the reasonable cost of performing the functions specified in subsection (a), and for the Federal Hospital Insurance Trust Fund's fair share of the costs attributable to the planning and other efforts directed toward coordination of activities in carrying out its agreement and other activities related to the provision of services similar to those for which payment may be made under part A, or related to the facilities and personnel required for the provision of such services, or related to improving the quality of such services.

(c) The Secretary is authorized to enter into an agreement with any State under which the appropriate State or local agency which performs the certification function described in subsection (a) will survey, on a selective sample basis (or where the Secretary finds that a survey is appropriate because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients), provider entities that, pursuant to section 1865(a)(1), are treated as meeting the conditions or requirements of this title. The Secretary shall pay for such services in the manner prescribed in subsection (b).

(d) The Secretary may not enter an agreement under this section with a State with respect to determining whether an institution therein is a skilled nursing facility unless the State meets the requirements specified in section 1819(e) and section 1819(g) and the establishment of remedies under sections 1819(h)(2)(B) and 1819(h)(2)(C) (relating to establishment and application of remedies).

(e) Notwithstanding any other provision of law, the Secretary may not impose, or require a State to impose, any fee on any facility or entity subject to a determination under subsection (a), or any renal dialysis facility subject to the requirements of section

1881(b)(1), for any such determination or any survey relating to determining the compliance of such facility or entity with any requirement of this title (other than any fee relating to section 353 of the Public Health Service Act).

EFFECT OF ACCREDITATION

SEC. 1865. (a)(1) If the Secretary finds that accreditation of a provider entity (as defined in paragraph (4)) by the American Osteopathic Association or any other national accreditation body demonstrates that all of the applicable conditions or requirements of this title (other than the requirements of section 1834(j)) are met or exceeded—

(A) in the case of a provider entity not described in paragraph (3)(B), the Secretary shall treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding; or

(B) in the case of a provider entity described in paragraph (3)(B), the Secretary may treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding.

(2) In making such a finding, the Secretary shall consider, among other factors with respect to a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation.

(3)(A) Except as provided in subparagraph (B), not later than 60 days after the date of receipt of a written request for a finding under paragraph (1) (with any documentation necessary to make a determination on the request), the Secretary shall publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing a period of at least 30 days for the public to comment on the request. The Secretary shall approve or deny a request for such a finding, and shall publish notice of such approval or denial, not later than 210 days after the date of receipt of the request (with such documentation). Such an approval shall be effective with respect to accreditation determinations made on or after such effective date (which may not be later than the date of publication of the approval) as the Secretary specifies in the publication notice.

(B) The 210-day and 60-day deadlines specified in subparagraph (A) shall not apply in the case of any request for a finding with respect to accreditation of a provider entity to which the conditions and requirements of sections 1819 and 1861(j) apply.

(4) For purposes of this section, the term "provider entity" means a provider of services, supplier, facility (including a renal dialysis facility), clinic, agency, or laboratory.

(b) The Secretary may not disclose any accreditation survey (other than a survey with respect to a home health agency *or, beginning on the date of the enactment of the HOSPICE Act, a hospice program*) made and released to the Secretary by the American Osteopathic Association or any other national accreditation body, of an entity accredited by such body, except that the Secretary may

disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary.

(c) Notwithstanding any other provision of this title, if the Secretary finds that a provider entity has significant deficiencies (as defined in regulations pertaining to health and safety), the entity shall, after the date of notice of such finding to the entity and for such period as may be prescribed in regulations, be deemed not to meet the conditions or requirements the entity has been treated as meeting pursuant to subsection (a)(1).

(d) For provisions relating to validation surveys of entities that are treated as meeting applicable conditions or requirements of this title pursuant to subsection (a)(1), see section 1864(c).

(e) With respect to an accreditation body that has received approval from the Secretary under subsection (a)(3)(A) for accreditation of provider entities that are required to meet the conditions and requirements under section 1881(b), in addition to review and oversight authorities otherwise applicable under this title, the Secretary shall (as the Secretary determines appropriate) conduct, with respect to such accreditation body and provider entities, any or all of the following as frequently as is otherwise required to be conducted under this title with respect to other accreditation bodies or other provider entities:

(1) Validation surveys referred to in subsection (d).

(2) Accreditation program reviews (as defined in section 488.8(c) of title 42 of the Code of Federal Regulations, or a successor regulation).

(3) Performance reviews (as defined in section 488.8(a) of title 42 of the Code of Federal Regulations, or a successor regulation).

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IMPROVING MEDICARE POST-ACUTE CARE TRANSFORMATION ACT OF 2014

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SEC. 3. HOSPICE CARE.

(a) HOSPICE SURVEY REQUIREMENT.—

(1) IN GENERAL.—Section 1861(dd)(4) of the Social Security Act (42 U.S.C. 1395x(dd)(4)) is amended by adding at the end the following new subparagraph:

"(C) Any entity that is certified as a hospice program shall be subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months beginning 6 months after the date of the enactment of this subparagraph and ending September 30, 2025.".

(2) FUNDING.—For purposes of carrying out subparagraph (C) of section 1861(dd)(4) of the Social Security Act (42 U.S.C. 1395x(dd)(4)), as added by paragraph (1), *and section 1822(a)(1) of such Act,* there shall be transferred from the Federal Hospital Insurance Trust Fund under section 1817 of such Act (42 U.S.C. 1395i) to the Centers for Medicare & Medicaid Services Program Management Account—

(A) $25,000,000 for fiscal years 2015 through 2017, to be made available for such purposes in equal parts for each such fiscal year; and

(B) $45,000,000 for fiscal years 2018 through 2025, to be made available for such purposes in equal parts for each such fiscal year.

(b) HOSPICE PROGRAM ELIGIBILITY RECERTIFICATION TECHNICAL CORRECTION TO APPLY LIMITATION ON LIABILITY OF BENEFICIARY RULES.—Section 1879 of the Social Security Act (42 U.S.C. 1395pp) is amended by adding at the end the following new subsection:

"(i) The provisions of this section shall apply with respect to a denial of a payment under this title by reason of section 1814(a)(7)(E) in the same manner as such provisions apply with respect to a denial of a payment under this title by reason of section 1862(a)(1).".

(c) REVISION TO REQUIREMENT FOR MEDICAL REVIEW OF CERTAIN HOSPICE CARE.—Section 1814(a)(7) of the Social Security Act (42 U.S.C. 1395f(a)(7)) is amended—

(1) in subparagraph (C), by striking "and" at the end;

(2) in subparagraph (D), in the matter preceding clause (i), by inserting "(and, in the case of clause (ii), before the date of enactment of subparagraph (E))" after "2011"; and

(3) by adding at the end the following new subparagraph:

"(E) on and after the date of enactment of this subparagraph, in the case of hospice care provided an individual for more than 180 days by a hospice program for which the number of such cases for such program comprises more than a percent (specified by the Secretary) of the total number of all cases of individuals provided hospice care by the program under this title, the hospice care provided to such individual is medically reviewed (in accordance with procedures established by the Secretary); and".

(d) UPDATE OF HOSPICE AGGREGATE PAYMENT CAP.—Section 1814(i)(2)(B) of the Social Security Act (42 U.S.C. 1395f(i)(2)(B)) is amended—

(1) by striking "(B) For purposes" and inserting "(B)(i) Except as provided in clause (ii), for purposes"; and

(2) by adding at the end the following:

"(ii) For purposes of subparagraph (A) for accounting years that end after September 30, 2016, and before October 1, 2025, the 'cap amount' is the cap amount under this subparagraph for the preceding accounting year updated by the percentage update to payment rates for hospice care under paragraph (1)(C) for services furnished during the fiscal year beginning on the October 1 preceding the beginning of the accounting year (including the application of any productivity or other adjustment under clause (iv) of that paragraph).

"(iii) For accounting years that end after September 30, 2025, the cap amount shall be computed under clause (i) as if clause (ii) had never applied.".

(e) MEDICARE IMPROVEMENT FUND.—Section 1898 of the Social Security Act (42 U.S.C. 1395iii) is amended—

(1) by amending the heading to read as follows: "**medicare improvement fund**";

(2) by amending subsection (a) to read as follows:

"(a) ESTABLISHMENT.—The Secretary shall establish under this title a Medicare Improvement Fund (in this section referred to as the 'Fund') which shall be available to the Secretary to make improvements under the original Medicare fee-for-service program under parts A and B for individuals entitled to, or enrolled for, benefits under part or enrolled under part B including adjustments to payments for items and services furnished by providers of services and suppliers under such original Medicare fee-for-service program.";

(3) in subsection (b)(1), by striking "during" and all that follows and inserting "during and after fiscal year 2020, $195,000,000."; and

(4) in subsection (b)(2), by striking "from the Federal" and all that follows and inserting "from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such proportion as the Secretary determines appropriate.".

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